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COVER NOTE

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COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements

Conclusions and Actions

{COM(2018) 116 final}

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GLOSSARY

ADCO	Administrative Cooperation Groups for European cooperation on market surveillance
ANSES	French Agency for Food, Environmental and Occupational health and Safety
ASO	Accredited Stakeholder Organisations
ATP	Adaptation to Technical Progress
BPR	Biocidal Products Regulation
C&L	Classification and Labelling
CA	Competent Authority
CAD	Chemical Agents Directive
CARACAL	Competent Authorities for REACH and CLP
CBA	Cost-benefit analysis
CCA	Cumulative cost assessment study
CCH	Conformity check
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CoRAP	Community Rolling Action Plan
COSME	Competitiveness of Small and Medium-sized Enterprises
CSR	Chemical Safety Report
DecaBDE	Decabromodiphenyl Ether
DMF	Dimethylfumarate
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECVAM	European Centre for the validation of alternative methods
EEA	European Environment Agency
EEB	European Environmental Bureau
EEN	Enterprise Europe Network
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENES	Exchange Network on Exposure Scenarios
EOGRTS	Extended One-Generation Reproductive Toxicity Study
ES	Exposure Scenario
ESR	Existing Substances Regulation
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
FCM	Food Contact Materials
FORUM	Forum for Exchange of Information on Enforcement
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

GDP	Gross domestic product
GPSD	General Product Safety Directive
HBCDD	Hexabromocyclododecane
HPVCs	High Production Volume Chemicals
IATA	Integrated Approach to Testing and Assessment
ICCM	International Conference on Chemicals Management
IOELVs	Indicative Occupational Exposure Limit Values
IOMC	Internet-based Toolbox for Decision Making in Chemicals Management
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
MS	Member State(s)
MSC	Member State Committee
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJEU	Official Journal of the European Union
OPC	Open Public Consultation
OSH	Occupational Safety and Health
PACT	Public Activities Coordination Tool
PBDEs	Polybrominated diphenyl ethers
PBDs	Polybrominated diphenyls
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCB	Polychlorinated biphenyl
PfAs	Proposals for Amendments
PFAS	Per and Perfluoro Alkyl substances
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
PPPR	Plant Protection Products Regulation
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
RMM	Risk management measure

RMOA	Regulatory Management Options Analysis
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
SAICM	United Nations Strategic Approach to Chemicals Management
SCCPs	Short chain chlorinated paraffins
SCOEL	Scientific Committee for Occupational Exposure Levels
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SMEs	Small and Medium Sized Enterprises
SVHC	Substance of Very High Concern
t/y	Tonnes per year
TSD	Toy Safety Directive
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
US EPA	Environmental Protection Agency of the United States
US	United States
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvBs	Very Persistent and Very Bioaccumulative substances
WEEE	Waste Electrical and Electronic Equipment
WHO	World Health Organisation
WoE	Weight of Evidence
WTO	World Trade Organisation

1. INTRODUCTION

The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH[1]) came into force in 2007 and aims at improving the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances while promoting alternative methods for the assessment of hazards of substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

1.1. Purpose of the REACH evaluation

The 2017 evaluation of the operation of REACH is part of the regular assessment and reporting by the European Commission on progress in achieving the objectives of the Regulation. This evaluation accompanies the second Commission report[2] on the functioning of REACH pursuant to Article 117(4) and Article 138 of REACH.

Regular monitoring and reporting provides information that allows for adjustment to improve the implementation of the Regulation. Being part of the Commission's Regulatory Fitness and Performance Programme (REFIT)[3], the 2017 REACH evaluation examines to what extent REACH is fit for purpose and looks at what works well and what does not, as well as why this is the case. In line with the Better Regulation Guidelines, the evaluation covers the five compulsory criteria: effectiveness, efficiency, relevance, coherence and EU added value, including the potential for burden reduction and simplification and improving the delivery of the objectives.

1.2. Scope of the REACH evaluation

The 2013 REACH review provided a first in-depth assessment of the overall operation of REACH, presenting a broad assessment of what the first five years of REACH had brought about. The 2017 REACH evaluation builds on those findings and examines key developments since then, in particular those that have emerged or developed substantially (e.g. the authorisation process); thus, mainly on the period 2010 - 2016, and assesses REACH's contribution to meeting the World Summit Sustainability Development 2020 goals and the Sustainable Development goals.

The 2017 REACH evaluation focuses on assessing the areas where there has been a sufficient level of implementation to allow for a meaningful evaluation at this stage. Some recent developments that are still in early stages of implementation (e.g. implementing regulation on data sharing) or that are being developed (amendment of technical annexes as regards nanomaterials) will be addressed to the extent possible[4].

The evaluation builds on information obtained from Member States, ECHA, a series of thematic studies and other relevant sources, covering the following aspects:

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[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[2] In 2013, the Commission published the first review of REACH – 2013 REACH review, a broad assessment of the first five years of REACH – COM(2013)49 final and SWD(2013)25final

[3] http://ec.europa.eu/smart-regulation/index_en.htm

[4] 2017 REACH evaluation Roadmap available at http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

I. Main issues resulting from the information obtained from regular reports from Member State Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and enforcement. These reports allow monitoring of the practical implementation of REACH and how it contributes to the protection of health and the environment in all Member States.

Member State reports provide an overview of the functioning of REACH in the territories of the 28 Member States and the EEA countries.

ECHA's reports provide an overview of the operation of REACH, including information on joint submission of information by multiple registrants (Article 11) and the state of use of non-animal testing.

Furthermore, Article 138 of the REACH Regulation specifies some elements that are relevant for the general REACH report, namely registration requirements for 1 – 10 tonnes substances, including the CSA and CSR obligation for substances that are carcinogenic, mutagenic or toxic to reproduction - CMRs category 1A or 1B.

II. The status of implementation of the work launched as a follow-up to the 2013 REACH review and the actions that the Commission, ECHA, the Member States, and, where relevant, stakeholders have already implemented or are implementing in that context. This includes also other significant legislative and policy developments since 2013, notably:

- Implementation of Roadmap on Substances of Very High Concern (SVHC) for 2020
- Streamlining of the restriction procedure
- Ongoing implementation work until 2017 on registration (including data sharing) and authorisation requirements with a view to improve effectiveness and lessen the administrative burden stemming from the Regulation.

III. Further detailed topics to be covered include:

- Assessment of the benefits of chemical legislation on human health and the environment as well as socio-economic benefits
- Assessment of the achievements made regarding the use of alternative test methods and non-test methods in REACH and in general
- Perception of chemical safety by citizens
- Support measures to assist SMEs (e.g. information concerning the use of EU funding programmes, guidance through the Europe Enterprise Network (EEN))
- Progress in the registration process, results of 2013 registrations and preparations for the 2018 deadline
- Review of the obligations on registration requirements for low tonnage (1-10 t/y) substances in relation to the REACH objectives
- Review of the obligations on the need, if any, to register certain types of polymers in relation to the REACH objectives
- Consideration of substance identity issues
- Assessment of the optimisation of substance evaluation
- Activities to improve the implementation of the requirements related to extended Safety Data Sheets (eSDS)
- Assessment of the costs and benefits of authorisation

- Interface with other legislation (including in particular the coherence between REACH and the occupational safety and health – OSH – legislation, coherence with legislation on waste as well as other relevant developments since 2013)
- Monitoring of enforcement of REACH via a new indicator system (and a public consultation on enforcement)
- Assessment of the impact of REACH on innovation, competitiveness and SMEs
- Assessment of the impact of REACH on the international competitiveness of the EU chemicals industry and selected Downstream User sectors
- Evaluation of ECHA and its Committees
- Information on substances in articles
- Review of Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency
- Ability of REACH to tackle nanomaterials, cumulative effects of chemicals, endocrine disruptors and other emerging issues

1.3. Co-ordinated strategy for ensuring chemicals legislation is fit for purpose

The EU legislative framework for the risk management of chemicals comprises a number of interacting and linked legal acts. These range from horizontal chemicals legislation (e.g. the Classification, Labelling and Packaging (CLP) Regulation) to product-specific and sectorial legislation, related to particular uses of chemicals in downstream industries. This is why a fitness check is also being undertaken of the wider legislative framework for the risk management of chemicals in the EU in parallel to the REACH evaluation, scheduled to finish in 2018[5].

The REACH evaluation focuses on the effects of REACH, whereas the fitness check focuses on the interactions between the different pieces of legislation. In contrast to the REACH evaluation, the fitness check does not carry out an evaluation of the individual pieces of legislation but rather focuses on specific elements within the legislation and the interlinkages between the pieces of legislation. In particular it:

- Assesses the consistency, effectiveness and efficiency of the chemicals legislation in applying generic risk and specific risk based risk management decisions;
- Assesses the accessibility of all relevant information available within the group of chemicals legislation when making a decision on a substance;

On the basis of a comprehensive impact assessment, the Commission is presently modifying the technical Annexes of REACH on substance identification, information requirements and chemicals safety assessment, to more effectively address nanomaterials when they are subject to registrations.

Additionally, the results of this evaluation and the Fitness Check will form the basis of a general stock-taking of the EU's existing legislative framework for chemicals risk management. It will also feed into the Commission's future chemicals strategy for achieving the objective of a non-toxic environment.

[5] Fitness Check Roadmap available at http://ec.europa.eu/DocsRoom/documents/21364

The obligation to report on the results of the official controls, and other enforcement measures taken under the CLP Regulation will be addressed under the fitness check exercise.

2. BACKGROUND

Increasing concerns that the pre-REACH EU chemicals acquis did not provide sufficient protection led to a debate at the informal Council of Environment Ministers in April 1998[6], in which it was recognised that a review of the existing policy on chemicals was necessary.

The reason for the pre-REACH policy debate was the slow progress of risk assessment under the Existing Substances Regulation (ESR – Regulation (EEC) No 793/93) and the implementation of risk management by e.g. Restrictions Directive (Directive No 76/769/EEC). The policy driver throughout was therefore the need to speed up the risk assessment and risk management of existing chemicals (i.e. those already on the market in 1981), but as the discussions progressed, other drivers and conditions were identified.

In line with dissatisfaction with the progress of ESR in 1999, the Joint Research Centre (JRC) published a technical study[7] showing that basic data necessary to carry out a screening level initial risk assessment was only publicly available for a minority of chemicals (less than 20%) and that this situation had not changed compared to what the US National Academy of Sciences had estimated to be the case in the 1980s. This added another, albeit related, policy driver, namely the need to obtain the necessary data for existing substances to enable the risk assessment and risk management of existing chemicals to take place.

The assessment of the functioning of the ESR showed that placing the responsibility on authorities to collect and assess the information on priority substances was ineffective. In fact, authorities needed to request industry to provide information to conduct risk assessments and decide on the need for risk management measures. This triggered the conclusion that, in line with the 'polluter pays principle', it should be the responsibility of industry to ensure the safe use of their chemicals and therefore carry out the risk assessment and ensure the risk management of their chemicals, including testing, and the responsibility of authorities to check if this responsibility is properly implemented and, where not, to quickly and efficiently propose measures to manage potential risks appropriately. Thus, the 'reversal of burden of proof' drove much of the design of REACH.

Though environment and health concerns related to the marketing and use of existing chemicals were the initial driver of the policy debate, that debate was also shaped by the general EU policy objectives of ensuring a level playing field in the EU (preserving the internal market), ensuring the competitiveness of EU industry and fostering innovation, being non-discriminatory internationally (respecting WTO) and promoting non animal test methods (supporting animal welfare). Furthermore, the legislation contributes to the

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[6] http://europa.eu/rapid/press-release_PRES-01-201_en.htm (CHEMICALS POLICY - Council Conclusions)

[7] JRC report on data availability for EU HPV; http://publications.jrc.ec.europa.eu/repository/handle/JRC27012; http://publications.jrc.ec.europa.eu/repository/handle/JRC27013

aim of the EU to achieve the goals agreed at the 2002 World Summit on Sustainable Development[8].

2.1. **Description of the initiative**

2.1.1. Objectives

The objectives of REACH are to ensure a high level of protection of human health and the environment, including the promotion of alternative methods to animal testing for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing the competitiveness and innovation. In addition, REACH should contribute to the fulfilment of the World Summit on Sustainable Development 2020 goals.

Protection of human health and the environment.

REACH replaced the previously existing Regulations, Directives, Communications and Recommendations governing so-called new and existing chemicals by one unified systematic registration system, ensuring that the same obligations apply to all chemicals. In line with the polluter pays principle, REACH shifted the burden of proof by making industry responsible for safety, extending responsibility along the supply chain. The registration system introduced requirements to make sufficient information available about the properties of all chemicals including for the previously so-called existing chemicals in order to conduct risk assessments and introduce risk reduction measures where so required for hazardous substances. Health and environment benefits should result from the application of appropriate risk reduction measures.

Harmonisation of the internal market.

REACH aims at harmonising the general chemicals legislation at Union level for all cases where no more specific product legislation exists that also concerns chemicals. This was implemented by choosing a Regulation based on Article 95 of the EC Treaty (now Article 114 TFEU), which ensures uniform application in all Member States, by establishing a central Agency, the European Chemicals Agency (ECHA) to implement most of the scientific and technical work and by establishing detailed rules for the manufacture, placing on the market and use of substances throughout the EU.

Enhancing competitiveness and innovation.

The Regulation was designed to shape the innovative behaviour of firms in the chemical industry as it ended the disadvantages of the previous system for new chemicals by raising the registration threshold to 1 tonne per year per company (compared to 10 kg before for new substances) and by requiring the same amount of data for new and existing chemicals. REACH should therefore promote the competitiveness of the chemical industry and encourage innovation, by facilitating the development of safer chemicals, in particular chemicals aimed at replacing substances of very high concern (SVHCs).

Promotion of non-animal testing.

Registrants are obliged to systematically collect all available information. Only where this information is insufficient to fulfil the information requirements should a test be considered. Furthermore most testing involving animals needs prior approval by ECHA

[8] Recital 4 of Regulation (EC) 1907/2006

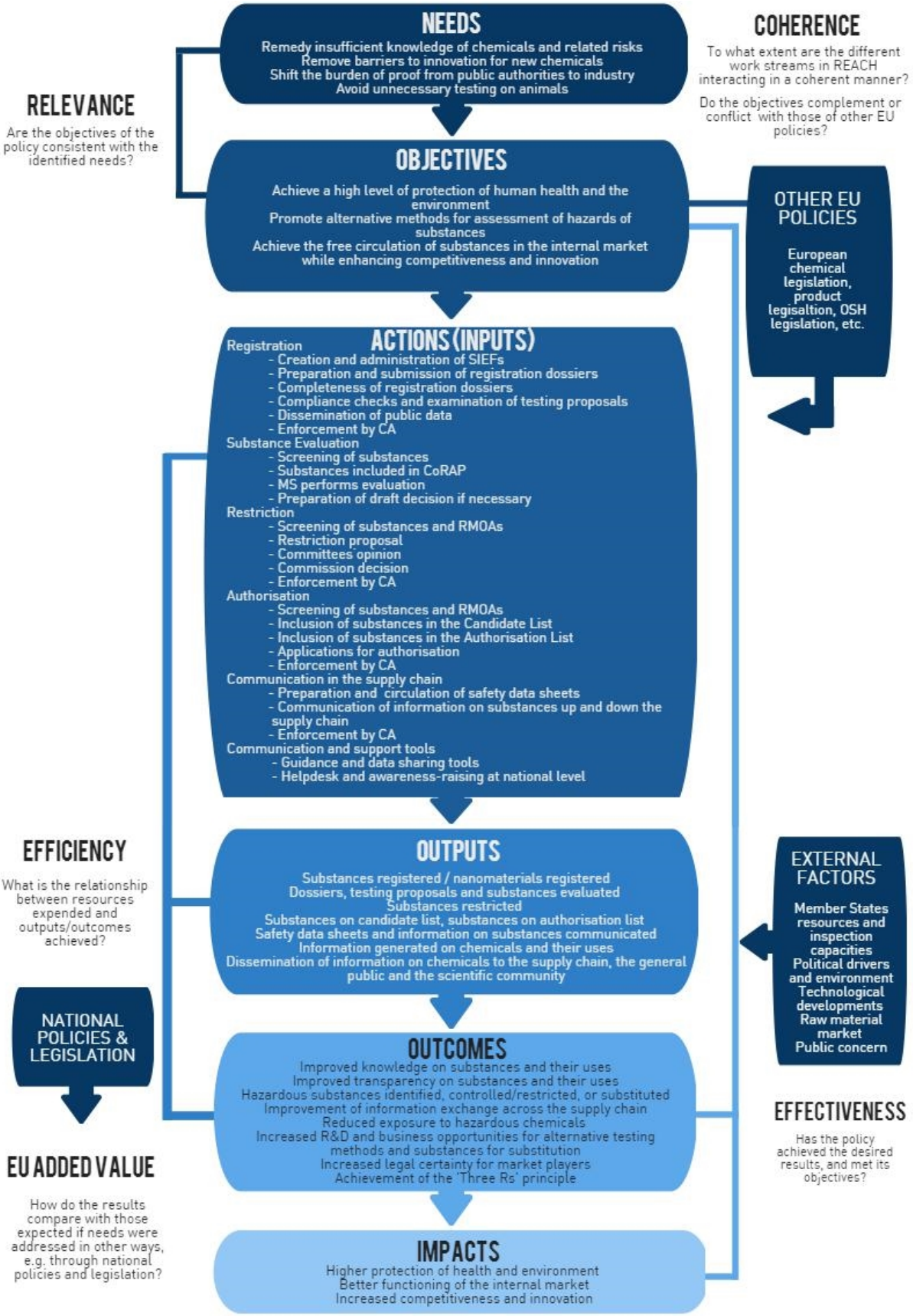
and legal possibilities to use alternative methods to fill information gaps (e.g. through read across, in vitro testing) were introduced to promote non-animal testing.

Separately the Commission has committed itself to stimulating and funding the development of new non-animal test methods.

2.1.2. Intervention Logic of the REACH Regulation

The intervention logic summarises how the intervention is envisaged to work. A visual representation is given of the logical links between the needs for the REACH Regulation, the objectives to be pursued, the actions taken by Member States, duty holders, the Commission and ECHA under each REACH process, the related output of these actions (e.g. substances registered or restricted) and general outcomes of the implementation and application of REACH (e.g. improved knowledge on substances, hazardous substances identified) leading to positive impacts on health, the environment and the functioning of the internal market as well as to enhanced competitiveness and innovation.

Figure 1: intervention logic of the REACH Regulation

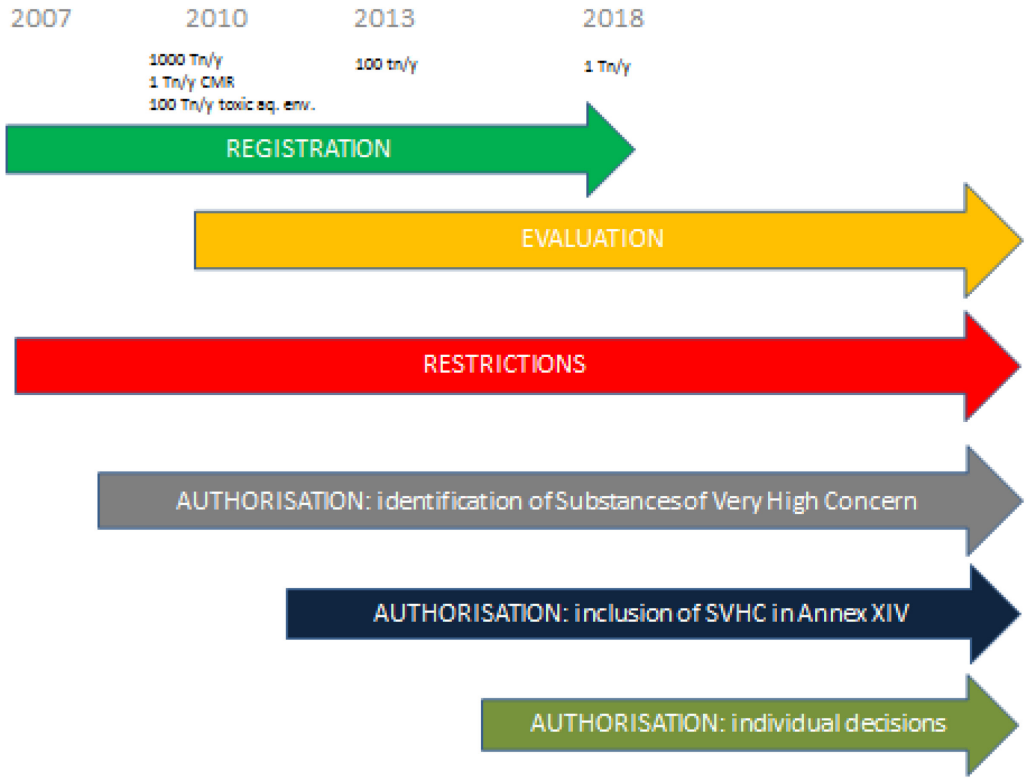

NEEDS
Remedy insufficient knowledge of chemicals and related risks
Remove barriers to innovation for new chemicals
Shift the burden of proof from public authorities to industry
Avoid unnecessary testing on animals
COHERENCE
To what extent are the different work streams in REACH interacting in a coherent manner?
Do the objectives complement or conflict with those of other EU policies?
RELEVANCE
Are the objectives of the policy consistent with the identified needs?
OBJECTIVES
Achieve a high level of protection of human health and the environment
Promote alternative methods for assessment of hazards of substances
Achieve the free circulation of substances in the internal market while enhancing competitiveness and innovation
OTHER EU POLICIES
European chemical legislation, product legisaltion, OSH legislation, etc.
ACTIONS (INPUTS)
Registration
- Creation and administration of SIEFs
- Preparation and submission of registration dossiers
- Completeness of registration dossiers
- Compliance checks and examination of testing proposals
- Dissemination of public data
- Enforcement by CA
Substance Evaluation
- Screening of substances
- Substances included in CoRAP
- MS performs evaluation
- Preparation of draft decision if necessary
Restriction
- Screening of substances and RMOAs
- Restriction proposal
- Committees opinion
- Commission decision
- Enforcement by CA
Authorisation
- Screening of substances and RMOAs
- Inclusion of substances in the Candidate List
- Inclusion of substances in the Authorisation List
- Applications for authorisation
- Enforcement by CA
Communication in the supply chain
- Preparation and circulation of safety data sheets
- Communication of information on substances up and down the supply chain
- Enforcement by CA
Communication and support tools
- Guidance and data sharing tools
- Helpdesk and awareness-raising at national level
EFFICIENCY
What is the relationship between resources expended and outputs/outcomes achieved?
OUTPUTS
Substances registered / nanomaterials registered
Dossiers, testing proposals and substances evaluated
Substances restricted
Substances on candidate list, substances on authorisation list
Safety data sheets and information on substances communicated
Information generated on chemicals and their uses
Dissemination of information on chemicals to the supply chain, the general public and the scientific community
EXTERNAL FACTORS
Member States resources and inspection capacities
Political drivers and environment
Technological developments
Raw material market
Public concern
NATIONAL POLICIES & LEGISLATION
OUTCOMES
Improved knowledge on substances and their uses
Improved transparency on substances and their uses
Hazardous substances identified, controlled/restricted, or substituted
Improvement of information exchange across the supply chain
Reduced exposure to hazardous chemicals
Increased R&D and business opportunities for alternative testing methods and substances for substitution
Increased legal certainty for market players
Achievement of the 'Three Rs' principle
EFFECTIVENESS
Has the policy achieved the desired results, and met its objectives?
EU ADDED VALUE
How do the results compare with those expected if needs were addressed in other ways, e.g. through national policies and legislation?
IMPACTS
Higher protection of health and environment
Better functioning of the internal market
Increased competitiveness and innovation

2.1.3. REACH elements

The REACH Regulation came into force in 2007 and aims at improving the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances it manufactures, uses or places on the market. Manufacturers and importers have to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in ECHA in Helsinki, Finland, to be able to manufacture, import or place on the market ("No data no market"). ECHA is the central point in the REACH system: it manages the databases necessary to operate the system, verifies that the data submitted complies with the requirements, and co-ordinates the in-depth evaluation of chemicals suspected to be of concern and is building up a public database in which consumers and professionals can find hazard information. The following section describes each of the main processes in REACH in greater detail and the timing of how they work together is illustrated in Figure 2 below.

Figure 2: Timelines for implementation of the main REACH processes.



It should be noted that some of the processes were new or had new elements and started immediately (such as registration), whereas others started only later (e.g. evaluation and

authorisation); others were a continuation from the pre-REACH system improved by a stronger integration of risk management with the risk identification process (e.g. restriction). Outputs and outcomes were expected to materialise with some delay, starting 10 years after the begin of the REACH implementation, and persisting for another 20 years, in particular actual benefits in terms of improved health and environment protection.

Registration, data sharing and avoidance of unnecessary testing

Industry has to provide information on all chemicals it places on the market in volumes at or higher than 1 tonne per company per year (t/y); special attention is given to long-term and chronic effects at the higher tonnages. The registration information requirements depend on the proven or suspected hazardous properties, on uses, exposure and volumes of chemicals that are produced or imported.

REACH puts the obligation on economic operators placing on the market hazardous substances and in particular for volumes above 10 t/y to apply a consistent and comprehensive approach to risk management in the chemical safety assessment (CSA) and to document the results in the chemical safety report (CSR) and the safety data sheet (SDS), containing also recommendations regarding the safe use of those chemicals which downstream users then must follow.

To ensure proportionality, the system provides for a tiered approach (information requirements depend on volume of substance manufactured or imported) and staggered registration deadlines, where high volume[9] and the most dangerous chemicals[10] had to be registered by the first registration deadline in 2010, followed by medium volume[11] substances in 2013 and lower volume[12] substances will follow in 2018.

Furthermore, under certain conditions, producers and importers of articles have to notify to ECHA the Substances of Very High Concern (SVHCs) listed on the candidate list[13] which are present in their articles.

To avoid unnecessary testing and reduce costs, data must be shared by companies registering the same substance. This is done in Substance Information Exchange Fora (SIEF) for substances already on the market when REACH entered into force (the so-called phase-in substances) or through the inquiry process for new substances (non phase-in substances). The data sharing obligations aim to ensure that studies, in particular those involving vertebrate animals, which are already available, are shared, as well as their costs. If the information is not available, potential registrants have to agree who will undertake the necessary testing and ensure that the test is carried out only once.

Information in the supply chain and downstream users

Improving the communication within the supply chain is a central theme of REACH. In the previous legislation, communication was required from the manufacturer or importer down the supply chain to downstream users in the form of Safety Data Sheets (SDS). As

[9] Above 1000Tn/year and registrant

[10] Carcinogenic, mutagenic and toxic for reproduction (CMR) and substances dangerous to aquatic organisms or the environment (the latter above 100 tonnes a year)

[11] Above 100Tn/year and registrant

[12] Above 1Tn/year and registrant

[13] SVHCs and candidate list are described later under authorisation

under the past legislation there were significant difficulties in obtaining information on the use of substances in the EU, a new requirement was introduced in REACH: Downstream users (DUs) and distributors have to communicate up the supply chain enabling registrants to better understand the uses of their substances for registration and thereby also increasing the knowledge of authorities about all uses of substances. This two-way communication aims at ensuring more transparency and safer use of chemicals in the EU, leading to more innovation and benefits for health and environment.

Some elements for this new communication approach are well-known, some have been newly introduced:

- SDSs were a well-accepted and effective tool before REACH. One of the major adaptations was the creation of the so-called "extended SDS" which is a SDS containing the relevant exposure scenarios from the CSR.
- A new obligation to provide information, *interalia* enabling appropriate risk management measures also for substances that do not require transmission of a SDS.
- The new duty for all suppliers of articles to communicate information on SVHCs present in articles above a concentration threshold of 0.1 % weight by weight to any recipient, including consumers who so request.

For the first time in chemical legislation, REACH made DUs a distinct category of duty holders and gave them an important role within its framework. In this respect, it is important to note that in REACH the concept of use is very wide, covering a very broad area of industrial and professional operations and processes extending far beyond the chemical industry. DUs have obligations and rights stemming from many REACH titles: registration (if not covered by their supplier), information in the supply chain, evaluation, authorisation, restrictions.

Dossier and Substance Evaluation

REACH provides that the ECHA, and the Member States can evaluate the information submitted by companies, examine the quality of the registration dossiers and the testing proposals contained therein.

Dossier evaluation covers two different processes:

- Examination of testing proposals submitted by registrants, where ECHA – in cooperation with the Member States - decides whether the tests are necessary and if so, under which conditions.
- Compliance check, where ECHA – in close cooperation with the Member States verifies and decides whether the information in the technical dossiers submitted by registrants meets the standard information requirements.

Under substance evaluation, Member States evaluate substances based on initial concerns to clarify whether their use poses a risk to human health or the environment. Registrants may be required to submit further information on the substance to assist this evaluation. In cooperation with the Member States, ECHA defines prioritisation criteria and then selects the substances that are to be evaluated following the opinion of the Member State Committee. The selected substances are listed by ECHA in the 'Community rolling

action plan' (CoRAP[14]). An evaluating Member State is designated for each substance on the final CoRAP.

Authorisation and restriction

REACH also aims at managing the risks from hazardous substances through the authorisation and restriction processes.

- The authorisation requirement aims to ensure the good functioning of the EU internal market while assuring that the risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. The authorisation procedure comprises several successive steps:

  - SVHC identification and candidate listing (on initiative of a Member State or ECHA on request from the Commission),
  - prioritisation and recommendation of substances for inclusion into Annex XIV (by ECHA),
  - inclusion in Annex XIV (by the Commission), thereby subjecting substances to the authorisation requirement. Once included in this Annex, a substance cannot be placed on the market for a use or used after a given date ('sunset date') unless the companies concerned are granted an authorisation for the specific use(s),
  - application for authorisation (by industry) followed by opinions by the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC) and
  - authorisation decisions (by the Commission following a vote by the Member States in the REACH Committee).

  Authorisation is a new process introduced by REACH, where operators need to have an authorisation for continued use of a substance based on a dossier prepared by them.

- The restriction process addresses unacceptable risks to human health or the environment posed by any substance that requires Union-wide action. The manufacture, use or placing on the market of those substances on their own, in mixtures or in articles may be restricted or even banned, if necessary.

  There was already an EU-wide restriction process under the pre-REACH system to address risks at EU level and ensure the proper functioning of the internal market. REACH introduced the possibility for Member States to initiate the restriction process. It sets out clear deadlines and was expected to considerably shorten the time between the moment the risk was identified and the adoption of the restriction. New restrictions may be proposed under different procedures:

  - the *standard* procedure, launched on the initiative of a Member State or by ECHA(acting on a request from the Commission[15]), which requires

[14] Community Rolling Action Plan

the preparation of an Annex XV dossier, public consultation, opinions by RAC and SEAC and the consultation of the Forum for Exchange of Information on Enforcement (Forum);

- the *simplified* procedure, for CMR substances with consumer uses[16], where there is no preparation of an Annex XV dossier and no involvement of the Committees;
- the procedure for substances subject to authorisation; if, after the sunset date, ECHA considers that the use of the substance in articles presents a risk that is not adequately controlled and ECHA prepares an Annex XV Dossier[17].

The European Chemicals Agency (ECHA)

The REACH Regulation set up a central entity for the administration of the system, the European Chemicals Agency. ECHA ensures the effective management of the technical, scientific, and administrative aspects of REACH, providing information on REACH to companies and the general public. It also develops IT tools and guidance documents to support industry and public authorities in fulfilling their obligations under REACH.

The organisational structure of ECHA has been adapted to reflect new tasks entrusted to it under the CLP Regulation, Biocidal Products (BPR)[18] and Prior Informed Consent (PIC) Regulation. ECHA's internal structure now comprises:

- A Management Board, responsible for adopting the financial planning, work programme, and annual reporting of ECHA, inter alia.
- An Executive Director: the legal representative of ECHA, responsible for the day to day management and administration of ECHA, including responsibility over its finances. The Executive Director reports to the Management Board.
- A Member State Committee (MSC), responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs), it also provides opinions on draft Decisions of ECHA on testing proposals, compliance checks and substance evaluation. If an unanimous agreement is not reached at the MSC, the matter is referred to the European Commission for decision making. The MSC also provides non-binding opinions on ECHA's draft recommendations on priority substances for inclusion into the authorisation list (Annex XIV) and on the draft Community Rolling Action Plans (CoRAP) of substances selected for evaluation.
- A Risk Assessment Committee (RAC), prepares the opinions of ECHA on hazard and risks of substances for human health and the environment in REACH processes, i.e. on applications for authorisation, on proposals for restrictions, and on other questions relating to risk assessment of proposed legislative action (on

[15] Article 68(1)

[16] Article 68(2)

[17] Article 69(2)

[18] ECHA's structure comprises also a Biocidal Products Committee to prepare opinions on applications for approval and renewal of active substances, identification of active substances which are candidates for substitution, applications for inclusion in Annex I, applications for Union authorisation, scientific and technical matters concerning mutual recognition.

request of ECHA's Executive Director)[19].The final decisions are taken by the European Commission. The members of RAC are appointed by ECHA's Management Board based on candidates nominated by the Members States.

- A Committee for Socio-economic Analysis (SEAC), prepares the opinions of ECHA related to the socio-economic impact on applications for authorisation, on proposals for restrictions and on other questions relating to the socio-economic impact of possible legislative action (on request of ECHA's Executive Director). The final decisions are taken by the European Commission. The members of SEAC are appointed by ECHA's Management Board based on candidates nominated by the Members States.
- A Forum for Exchange of Information on Enforcement to coordinate a network of Member State competent authorities responsible for enforcement. The Forum is composed of one representative from each Member State.
- A Secretariat, under the leadership of the Executive Director, to support the Committees and Forum, and to undertake work on registration and evaluation processes as well as the preparation of guidance, maintenance of databases and provision of information.
- A Board of Appeal, to decide on appeals against certain decisions taken by ECHA.

Member States

Member States have established national helpdesks[20] to provide advice to duty holders concerning their obligations under REACH. National helpdesks are part of the HelpNet network, hosted by ECHA that promotes the provision of uniform advice to companies.

Member States have also appointed the Competent Authorities responsible for performing the tasks stipulated in the Regulation, in particular concerning evaluation, restrictions and authorisation, as well as for cooperating with the Commission and ECHA in its implementation. The Member States have to ensure that the Competent Authorities are sufficiently resourced to support their ECHA Committee Members and can fulfil their duties to prepare restrictions, identification of substances as SVHC, or proposals for harmonised classification and labelling.

Member States' authorities are responsible for enforcement by conducting official controls and establishing penalties for non-compliance. They exchange information and coordinate their enforcement activities through the Forum for Exchange of Information on Enforcement[21].

European Commission

The Commission has the ultimate responsibility to take decisions on risk management measures (such as restrictions and authorisations), and takes decisions under the

[19] RAC also prepares opinions of ECHA on proposals for harmonised classification under CLP

[20] The countries of the European Union, Norway, Iceland and Liechtenstein run helpdesks who give support on questions related to REACH obligations. In many cases, they are located in national competent authorities. These national helpdesks are the first point of contact for companies based in those countries.

[21] More information is available on the website of the Forum for Exchange of Information on Enforcement

evaluation process, where ECHA does not succeed to decide due to lack of unanimity in its Member States Committee.

The Commission has the right of initative related to risk management measures: it can initiate the restriction process (either directly or via ECHA), and it can request ECHA to initiate the process for the identification of substances of very high concern.

Furthermore, the Commission oversees activities to ensure the harmonised implementation of REACH by organising regular meetings of the competent authorities where all issues requiring agreements among the authorities, such as interpretative questions, are discussed.

Lastly, the Commission has to monitor the operation of the Regulation and is empowered to adopt amendments to its Annexes for adaptation to technical progress. The Commission is also empowered to adopt regulations to supplement the REACH Regulation (e.g. through Regulations on test methods, fees and charges) and implementing Regulations (e.g. data sharing).

2.2. An overview of the chemical industry and related sectors

The chemical industry is one of Europe's largest manufacturing sectors, with annual EU chemical sales estimated at EUR 519 billion[22], equivalent to around 14.7% of global sales. While absolute sale figures remained relatively stable over the last ten years, EU production has fallen strongly as a percentage of the global market as a result of the growth of emerging markets, especially China. The sector comprises over 28,000 companies, who employ around 1.13 million persons. Around 96% of European chemical companies are SMEs. They provide more than one third of all the industry's employment and generate about one third of the sector's value added. The sector generates a value added of about EUR 115 billion[23] (representing about 0.8% of EU GDP) and has a trade surplus of over EUR 40 billion per year. In 2016, extra-EU chemicals exports were EUR 146.3 billion and extra-EU imports reached EUR 98.6 billion.

Besides the chemical industry described above, one of the manufacturing sectors considered to be most directly affected by REACH is metal manufacturing. Altogether, those two sectors (chemical industry and metal manufacturing) account for a comparable proportion of GDP, contribute roughly EUR 126 billion in Gross Value Added, and account for around 1.5 million jobs[24].

As an "enabling industry", the chemical industry is at the heart of the EU manufacturing industry, supplying two-thirds of its production to other sectors within the manufacturing industry. Thus, a large range of downstream sectors rely on the use of chemicals in their everyday activities, such as the automotive and aerospace sectors, the paper and pulp sector, as well as the manufacture of everyday goods such as textiles, cosmetics, toys, etc. Other important links exist with agriculture activities and services.[25] It should be

[22]Estimations by CEFIC for 2015, based on NACE 20

[23] Eurostat 2014 figure for NACE 20

[24] Fitness Check final report

[25] Further details and economic figures are provided and analysed under the sections dealing with internal market and competitiveness

noted that REACH does not only affect the chemicals industry, but also all of these downstream user industries.

2.3. Baseline: pre-REACH (extended Impact Assessment) and the 2013 REACH review

In order to assess the progress of REACH over its full 10 years this second REACH evaluation uses the pre-REACH situation and the expectations foreseen in the original extended impact assessment[26]or the estimates for ECHA annual workload[27] as the baseline. At the time, estimations were made on the costs of REACH, the number of substances that would be registered and the timing and the subsequent regulatory REACH measures

That baseline has already been considered, through the first assessment of the implementation of REACH that was carried out after five years of operation of the Regulation and published in 2013 – the "REACH Review 2013"[28]. The Commission undertook a broad assessment based on Member State and ECHA reports, as well as thematic studies carried out by external consultants under the supervision of the relevant units of the Commission.

The REACH Review 2013 concluded that REACH functioned well and delivered on all objectives that could be assessed at that time. Some needs for adjustment were identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concluded that changes to the enacting terms of REACH would not be necessary.

The Commission noted however, a need to reduce the impact of REACH on SMEs and set out measures that would contribute to that goal. Many other opportunities for improvement at all levels were set out in the Commission Report and were further described in a Staff Working Document. Where relevant, the state of play of implementation of the different REACH chapters at the time of the REACH Review 2013 is also taken into account for this REFIT evaluation.

3. EVALUATION QUESTIONS

The Commission services will examine the effectiveness, efficiency, proportionality, coherence, relevance and EU added value of the provisions of the REACH Regulation, focusing on the elements set out in the previous sections. The evaluation will be guided by the following questions:

3.1.1. Effectiveness

1. To what extent does REACH meet its objectives?

[26] SEC (2003) 1171

[27] 2006 Revised Legislative Financial Statement – SEC(2006)924 2006 Revised Legislative Financial Statement – SEC(2006)924

[28] COM (2013) 49 final and SWD (2013) 25 final

2. What have been the effects of REACH (whether socio-economic, environmental or health-related, both positive and negative), including also effects not originally planned?
3. What factors (including external ones) influenced the observed effects and to what extent?
4. To what extent is REACH contributing to meeting the World Summit Sustainability Development 2020 goals?

3.1.2. Efficiency

1. What are the costs and benefits associated with the implementation of REACH? To what extent are the costs proportionate to the benefits achieved?
2. What are the key drivers for those costs and benefits? What factors influenced the efficiency with which the accomplishments of REACH were attained?
3. Was the distribution of costs proportionate between the different stakeholders (e.g. larger companies vs. SMEs, or among different industrial sectors)? To what extent are there unnecessary burdens on stakeholders?
4. How are costs distributed among public authorities at EU and national levels?
5. What aspects of REACH (including procedural aspects) are the most efficient and what are the least efficient (including the development of scientific opinions, work of scientific committees, urgency procedures, etc.)? Are there case studies demonstrating highly efficient or inefficient working of REACH processes? Are there differences in efficiency between Member States (both in terms of delivery of objectives and the costs of doing so)?

3.1.3. Coherence

1. To what extent are the different work processes, including their output, in REACH interacting in a coherent manner?
2. The REACH review 2013 examined the coherence of REACH with other chemical legislation. To what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?
3. To what extent is REACH coherent with international efforts, including chemical legislation in third countries?

3.1.4. Relevance

1. To what extent is REACH capable of adapting to evolving needs (e.g. through adaptations to technical and scientific progress)?
2. To what extent is REACH relevant to the EU and its citizens?
3. To what extent is REACH capable of taking into account health, consumer and environmental concerns, and social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?

3.1.5. EU added value

1. What is the additional value of regulating the risk management of chemicals at EU rather than at Member State level?

4. METHODOLOGY

4.1. Evidence collected since 2013

The first REACH review concluded that more information was necessary to determine whether to review information requirements for the registration of substances produced in low tonnages and of certain polymers. In addition, the Commission proposed a more systematic approach concerning the collection of information and reporting on Member States' activities, including their enforcement activities, as well as work to address difficulties in relation to substance identity and sameness. Moreover, there was a need to improve the methodology to assess and quantify the benefits arising from the implementation of REACH.

The need to monitor regularly the effects of the implementation of REACH was also highlighted in the REACH review 2013, in particular as regards industry preparedness for the 2013 and 2018 registration deadlines, and effects on innovation, SMEs and international competitiveness. A number of thematic studies were launched in those areas as a follow-up to the REACH review 2013 (overview in Annex 3).

As well as those thematic studies, extensive evidence on the functioning of REACH is periodically reported to the Commission by Member States and ECHA in accordance with the requirements of Article 117 of the Regulation. Member States submitted their latest reports in 2015, while ECHA submitted its report on the functioning of REACH in 2016 and two reports on the use of alternative methods to animal testing (in 2014 and in 2017). In addition, ECHA published reports and other relevant documents[29] on particular areas of REACH implementation that present additional evidence for this REFIT evaluation.

A wide range of stakeholders (companies, associations, NGOs, trade unions, MSs etc) exchange views regularly[30] with the Commission services, highlighting key issues in relation to the implementation of REACH. In this context, the Commission has underlined the importance of presenting data to describe and possibly quantify the issues raised when providing input for the REACH evaluation process.

Several thematic studies were launched in the course of 2015 and 2016 in order to further develop the knowledge and evidence base for the second REACH review. Those studies aimed to enable the Commission services to undertake a systematic analysis, address information gaps and monitor progress towards achievement of the REACH objectives. In particular, studies were designed to monitor reduction of risks and improvement of the quality of data available for chemical risk assessment, to review the performance of ECHA and to assess the impacts of the authorisation process. All relevant details can be found in Annex 3.

A roadmap[31] was developed and published presenting the key questions to be addressed by the evaluation, as well as a consultation strategy to ensure stakeholders' engagement in the evaluation process.

[29] E.g. annual reports, implementation report for the SVHC roadmap, regulatory strategies

[30] E.g. Competent Authorities for REACH and CLP (CARACAL)

[31] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

The Commission Services involved in the development of REACH and its implementation over the last 10 years have accumulated significant experience and insights to the implementation and functioning of REACH. This experience and insights are also used in this evaluation to draw conclusions and identify key findings to prioritise for immediate action. Priorities were established on the basis of the main shortcomings with the implementation of REACH in the last five years, considering also the concerns raised by stakeholders.

4.1.1. Approach to quantification

The REACH Regulation provides a comprehensive regulatory system expected to deliver short term benefits but also long-term benefits, such as positive effects on human health, which were expected to materialise 10 years after the start of REACH implementation. On the other hand, other effects such as the costs and resources necessary for companies and public authorities to adapt to the requirements of REACH materialise immediately. In spite of the experience gained so far, the implementation of REACH is still in a relatively early stage and benefits are only starting to materialise and cannot yet be quantified; accordingly, at this stage, the evaluation does not (and cannot) aim for a full quantitative comparison of benefits with costs.

The evaluation thus focuses on monitoring progress, assessing the outcomes of the intervention so far and comparing those results with expectations. A first strand of work is comparing the costs (to the extent that relevant costs can be quantified) with the expectations stated in the Impact Assessment for the REACH proposal. Moreover, attempts to qualify and quantify benefits have been carried out, while keeping in mind the present limitations. In addition, the evaluation seeks to identify key issues and opportunities for improvement in all areas of REACH implementation.

4.1.2. Data collection[32]

Several thematic studies (see Annex 3 for the details of the 16 studies) have been carried out by external consultants for the Commission services. The main methodologies applied in the context of those studies are described below:

- Desk research was conducted in the early stages of most thematic studies in order to review existing literature, gather available data and identify information gaps that would need to be filled. Reports from Member States and ECHA were also analysed to extract key issues and data. Results from ECHA meta-analysis studies were also used to derive costs and benefits for the authorisation and restriction processes
- Surveys were conducted in several studies in order to gather information available from particular stakeholders (e.g. costs information from companies) as well as to get a systematic collection of stakeholders' views on specific areas (e.g. performance of ECHA).
- Interviews have been conducted in several studies to complement surveys and obtain in-depth insights into issues raised by stakeholders in the context of surveys.

[32] An extensive list of the studies used as evidence-base for the REACH evaluation is included in Annex 3 to this Staff Working Document, including details about the individual approach and methodology for data collection and models applied by each study. All studies are publicly available in the webpage of the REACH evaluation (http://ec.europa.eu/DocsRoom/documents/26825)

- Workshops and ad hoc focus groups were arranged in the context of several studies to discuss the early findings and obtain feedback and additional expert opinions on the topics addressed by the studies.

According to the objectives stated in the consultation strategy[33] for the REACH evaluation, stakeholder consultation is a key component to gather evidence, data and information on REACH implementation. Thus, a structured approach was developed to collect information from stakeholders. Feedback from all the categories of stakeholders identified in the consultation strategy has been obtained through the consultation activities carried out.

Table 1: Feedback collected through consultation activities by stakeholder group

	Public authorities	**Industry associations**	**Companies / SMEs**	**Civil society (NGOs)**	**Consumer associations**	**Trade unions**	**Consumers / workers / citizens**	**Third countries**
Online public consultation	√	√	√	√	√	√	√	√
SME panel			√					
Stakeholder questionnaires	√	√		√	√	√		√
Stakeholder interviews	√	√		√	√	√		√
Stakeholder workshop	√	√		√	√	√		
Expert group	√	√		√				√
Eurobarometer Survey							√	

Annex 2 to this report provides a detailed summary of the consultation activities and results obtained, including the online public consultation and SME consultation that ran between the end of October 2016 and the end of January 2017.

4.1.3. Limitations and robustness of findings

Despite best efforts, there are a number of challenges in the analysis:

- While extensive information on the functioning of REACH is available, it is often rather general, based on individual appreciations and it is difficult to say how representative these views or examples are. Thus, one of the difficulties for the evaluation was to extract relevant, robust and reliable evidence from a "large pool of information" that would allow a qualitative and quantitative description of the effects of REACH. Therefore great care was taken to accurately report the context and relevance of reported information.
- The relatively early stage of implementation mentioned above is one of the challenges for a comprehensive evaluation of REACH and in particular its benefits. It is acknowledged that some benefits will still manifest in the next 10 years.
- The complexity and far-reaching effects of REACH, affecting society and a broad range of sectors well beyond the chemical industry as well as the environment make it difficult to provide a systematic and detailed account of all the effects. Therefore the evaluation concentrates on the main objectives of REACH.

[33] Published at http://ec.europa.eu/DocsRoom/documents/17785

- Verified data are difficult to obtain. Efforts were made to estimate costs using a statistically robust sample of respondents and, where possible, to crosscheck with findings of previous studies on the implementation of REACH or additional sources of data. However, cost estimates often rely on data collected through company surveys with limited possibilities to establish whether questions have been understood in the same way, and whether the data are representative, or to compare and validate them.
- Finally, assessing causality between REACH and the effects observed on the ground is not straightforward. REACH in itself is complex but it is also designed to complement obligations stemming from a multiplicity of other EU legislation and national rules. An economic operator therefore often does not clearly understand if an obligation actually stems from another piece of legislation or from REACH. In addition REACH replaced a significant number of directives and regulations and therefore the assessment of REACH needs to disentangle the baseline (continuation of the pre-REACH legislation) from the additions coming from REACH. In addition, there are a large number of intervening factors at play (e.g. economic cycles, evolution of chemical markets worldwide) making it very difficult to attribute the parts of an observed effect to REACH.

5. IMPLEMENTATION STATE OF PLAY

This section provides an overview of the state of implementation of REACH, presenting key findings on the main chapters of the Regulation. A detailed analysis and evaluation of the technical dimension of the implementation of each chapter is presented in Annex 4.

5.1. Registration

A key chapter of REACH is the requirement for registration of substances. The main aim of registration under REACH is to ensure that industry adequately manages the risks from its substances by obtaining adequate data, by performing chemical safety assessments, by implementing appropriate risk management measures and by submitting a registration to ECHA which documents all of these.

The first registration deadline in 2010 was assessed as part of the 2013 REACH Review, which drew a number of conclusions on, for example, compliance of registration dossiers. The second registration deadline was in 2013 (after adoption of the REACH Review) and the third deadline is in 2018.

Since the 2013 REACH Review progress can be observed on how industry fulfils its obligations as regards submission of dossiers and how more data are becoming available for the risk assessment of chemicals. Generally, the system is working well and as envisaged; however, some issues have been identified in particular in relation to the quality of dossiers. The costs of registrations are dealt with in Annex 4 - part of registration and in efficiency questions.

Key findings on the implementation of registration include:

- Registration is taking place. By December 2017[34], ECHA had received and disseminated more than 65 000 dossiers for approximately 17 000 unique registered substances since REACH came into operation, which is broadly in line with the original estimates of the Commission. The 'one substance, one registration' principle is largely respected, and is being further promoted.
- The availability of data for risk management (through registration dossiers) is improving as seen in the quality scores[35]. In particular availability of exposure scenarios has improved. This is making more information available to manage the risks from substances.
- Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action.
- The update of registration dossiers by companies is still a weak point, only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA. ECHA concluded in 2016 that stronger incentives may be needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. The only incentive working in practice might be enforcement actions by the Member State Competent Authorities on dossiers which updates are overdue.
- REACH provisions concerning the registration of intermediates[36] are not fully coherent and have caused uncertainty for both registrants and regulators.
- A review of the Commission Recommendation on the definition of a nanomaterial is ongoing. Work is also ongoing for the amendment of Annexes to the REACH Regulation to clarify the registration requirements for nanoforms of substances.
- Further work is needed for the development of a useful system for the possible registration of polymers of concern for human health and/or environment, taking account of competitiveness and innovation.
- Two changes to the registration requirements in the low tonnage band (1-10t) are being considered by the Commission to improve risk management of hazardous substances due for registration by 2018; increasing standard information requirements and obliging the Chemical Safety Report for the CMR 1A or 1B. Both need further study to assess the affordability for SMEs.
- In the light of data-sharing obligations that will continue to apply for registration and evaluation, the consequences of the time limitation of the obligation for SIEFs to stay operational until 1 June 2018 as stated in Article 29 of REACH need further consideration.

[34] More information available on ECHA's website: Registration statistics infograph - ECHA

[35] REACH Baseline study: 10 years update (2017) - http://ec.europa.eu/growth/sectors/chemicals/reach/studies_en

[36] A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (Article 3 (15)).

- There is work ongoing to improve the completeness and compliance of registration dossiers and to support the 2018 registration deadline, which is expected to involve a large number of SMEs.

5.2. Data sharing, test methods and avoidance of unnecessary testing

The hazardous properties of chemicals cannot be sufficiently determined using currently available in vitro (non-animal) testing methods. As REACH requires information to be gathered, the implication would be an increased use of laboratory animals. To minimise animal testing, REACH requires companies to share data and obtain approval in advance for certain tests. The Commission is also active in the field of developing, validating and promoting the regulatory use of alternative test methods, for example through the Framework Programme for Research and the European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM).

Key findings on the implementation of data sharing, test methods and the avoidance of unnecessary testing include:

- Since the 2013 REACH Review, the data sharing process has been further improved, and is the most important contributor to avoiding animal testing.

- The REACH principles of sharing and joint submission of data on intrinsic properties of a substance generally work well. Data sharing between structurally similar substances suitable for read across and categorisation purposes has the potential to further avoid animal testing and also to identify hazards earlier and thereby manage risks faster, but is hampered by the absence of obligatory data sharing between structurally similar substances in REACH.
- Amendments to the standard information requirements have introduced test methods that lead to a reduction or replacement of testing on vertebrate animals, such as the requirement for the extended one-generation reproductive toxicity study (EOGRTS). However, test methods containing optional modulation, as in the case of EOGRTS, cause difficulties in implementation and may lead to re-testing should conditions change.
- 38 new (alternative) test methods have been introduced in Regulation (EC) No 440/2008 and 24 methods have been updated in the last 5 years via Adaptations to Technical Progress (ATPs); these methods were first endorsed by the OECD Test Guidelines Programme. ECHA and the Commission's Joint Research centre provide initial advice on new OECD Test Guidelines and their possible use for the purpose of REACH, while inclusion in the Regulation provides legal clarity but only after a time- and resource-intensive process. Further assessment is needed to determine whether the current process can be improved, in particular in terms of regulatory readiness and regulatory acceptance of alternative methods and whether the process could be further optimised while retaining scientific soundness and legal certainty.
- Information from the third ECHA report[37] on the use of alternatives to testing on animals for the REACH Regulation confirms that the main source of experimental data for low tier endpoints are studies performed before REACH came into force.

[37] Link to Third ECHA report on the use of alternatives to animal testing

Endpoints outlined in REACH Annexes VII and VIII are considered as low-tier endpoints, while endpoints listed in REACH Annexes IX and X are considered as high tier endpoints. Less experimental data is available for high tier human health endpoints. For high tier environmental endpoints adaptations (such as QSAR or read across) are much more common than experimental data. This report also shows a continued high use of the adaptation possibilities offered in Annex XI, in particular read-across. This confirms that many registrants seriously implement the legal requirements to propose testing on animals only as a last resort. However, the adaptations used by registrants have often been found to be insufficiently justified, especially when the conclusion is the absence of a given hazard and in case of non-compliance, further testing is requested. ECHA has recently increased efforts to provide improved information and guidance to registrants, in order to improve the quality of adaptations. Consequently, less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted.

- Although validated and accepted alternative test methods are available for certain endpoints (notably skin and eye irritation), and these methods are frequently used in REACH Registration dossiers, there are still a significant number of recent in vivo tests submitted for those endpoints. The reasons for this need to be further explored in detail, but limited analyses point to regulatory requirements in third countries as an important driver for animal testing, highlighting the need to further work towards the international acceptance of alternative methods.
- The Commission makes significant and sustained financial efforts to support the research on alternative methods, as well as the subsequent steps (e.g. validation and test guideline development) leading to regulatory acceptance. During the period 2012-2016, Commission expenditure has been around EUR 40 million per annum. However, there are still gaps in terms of alternatives for some endpoints.

5.3. Communication of information in the supply chain

Communication within the supply chain is a central theme in REACH, as it ensures the passing on of information on hazards of substances, risks associated with their use and the necessary risk management measures down the supply chain to ensure safe use. In addition, downstream users need to pass information on how they use chemicals up the supply chain.

Since the 2013 REACH Review efforts have been made to improve communication along the supply chain. Companies are increasingly engaged in the elaboration and transmission of extended safety data sheets (SDSs), with the support of different activities launched by ECHA (see Annex 4, paragraphs 3.1.1 and 3.1.2 for more details), resulting in improved communication promoting safer use of chemicals including complying with the requirements of occupational safety and health legislation. However, information flows do not always work well.

Key findings on information in the supply chain include:

- The introduction of extended SDS has led to improvements in communication and more transparency in the supply chain. Around a half of companies have adopted changes in risk management measures on the basis of information received via extended SDS. However, in a significant number of cases, the information

communicated is too lengthy and technical, or does not provide enough practical information to implement appropriate risk management measures.

- Responding to the problems identified in the 2013 REACH Review, a number of tools have been put in place to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS. These appear to be having a positive effect, but could be more fully used.
- Many companies, and in particular SMEs, consider extended SDS as burdensome and too technical to be fully understood mainly due to lack of in-house expertise. This prevents SMEs from using the information on the properties and use of substances in order to manage risks at their workplaces. In some cases the lack of information or the poor quality of particular exposure scenarios was underscored as an obstacle for formulators to prepare good quality SDS for their mixtures. The costs associated with the obligation to transmit information in the supply chain (which includes management of extended SDS and their translation) was also raised as problematic, in particular as most of the transmission is currently done manually (i.e. on paper).

5.4. Information on substances in articles

Producers and importers have to notify to ECHA the substances listed on the Candidate list which are present in their articles, under certain conditions:

- The substance is present in their relevant articles above a concentration of 0.1% weight by weight.
- The substance is present in these relevant articles in quantities totalling over one tonne per year.

The notification information can be used together with other sources (e.g. registration information) to support identification of further needs for risk management. If there are grounds for suspecting that the substance is released from the articles under normal or reasonably foreseeable conditions of use and such a release presents a risk to human health or the environment, then the producer or importer of articles may be required to submit a registration.

Since the 2013 REACH Review progress can be observed as to how industry fulfils its obligations as regards substances in articles, and how this information is communicated and used. However, whilst the situation may be improving, it is still not working as well as originally envisaged.

Key findings on substances in articles include:

- Divergence between Member States in the interpretation of the 0.1% threshold limit regarding notifications to be submitted to ECHA (Article 7(2)) and regarding communication in the supply chain and to consumers (Article 33) of REACH has been resolved by a ruling of the European Court of Justice. This provides a common basis for the harmonised implementation of the requirements related to SVHCs in articles, and for increased and coordinated enforcement activities.
- The amount and adequacy of information in registrations dossiers for the safe use of substances in articles is still very limited. Fewer than expected notifications to ECHA have been provided, because of: a lack of awareness; difficulties to get the information needed, especially from third country suppliers; descriptions of uses in articles in registration dossiers being too broad; costs of communication for example

due to complexity; a lack of methods to assess the safety of substance uses in articles (e.g. release and exposure estimation methods); a lack of methods to measure the content and release of SVHCs in articles. This limits the usefulness of such information for the identification of appropriate regulatory measures.

- The obligations to communicate the presence of SVHCs in articles allows operators along the supply chain to implement appropriate risk management measures as well as enabling operators and consumers to make informed purchasing decisions. This is happening, as information flows improve, but slower than foreseen reflecting perhaps the costs of managing the information flows and the need to learn from experience.
- Efficient functioning of supply chain communication is necessary for economic operators to implement appropriate risk management measures and to make informed purchasing decisions as well as for the ability of suppliers to respond to consumer requests. The communication requirement in Article 33 has triggered the development and potential use of information management tools by companies promoted by EU-projects or activities of some Member States. However, it remains difficult for actors in the supply chain to retrieve, verify and communicate information on SVHCs in articles. The transfer of information to the consumer greatly depends on a well-functioning communication in the supply chain as well as on the awareness and understanding of consumers about their "right to know".
- Better tracking of chemicals of concern in products would facilitate recycling and improve the uptake of secondary raw materials, as part of the Circular Economy. However, this would require transfer of information on the chemical content of end-of-life articles to the waste management sector.

5.5. Substance and dossier evaluation

Evaluation is a set of processes in which ECHA and the Member States evaluate the information submitted by companies in registration dossiers to (1) under dossier evaluation, check compliance of the registration dossiers and examine the registrant's testing proposals for higher tier studies that require the use of vertebrate animals[38], and to (2) clarify under substance evaluation if the use of a given substance constitutes a risk to human health or the environment.

The evaluation processes often result in legally binding decisions whereby registrants are required to update their dossier(s) with further information on the substance within a specified deadline. Further regulatory risk management action(s) may be initiated by the authorities as a follow-up of the evaluation conclusions.

Both dossier and substance evaluation processes are operational and contributing to an important extent to the generation of relevant data on chemicals. Both processes are continuously evolving as challenges are identified and addressed on the basis of experience. This however requires time and resources from ECHA, the Member States and the industry. Further modifications to the existing procedures could be considered to improve the level of efficiency and effectiveness.

[38]In case information (study) is not already available, it must be proposed, unless an adaptation is provided, in accordance with the general rules for adaptation set out in Annex XI to REACH or the specific rules for adaptation set out in column 2 of Annexes VII to X to REACH.

Key findings on the implementation of dossier and substance evaluation include:

The integrated regulatory strategy developed by ECHA[39] provides an adequate framework to identify and prioritise "substances that matter".

- By the end of 2016, in terms of dossier evaluation, 748 testing proposal examination decisions had taken place. Around 220 compliance checks a year were taking place. Follow up to dossier evaluation decisions is an increasingly important part of ECHA's work. There are technical challenges, such as the changes in the reproductive testing approach. These need to be addressed given that dossier evaluation is the main means to ensure the required information is being gathered in registration, which has a direct impact on ensuring REACH delivers its objectives.
- Fewer substance evaluations have taken place than predicted, with 82 decisions by ECHA on substance evaluation adopted so far. This falls far short of expectations of 448 substances evaluated by 2016. If more substances would be evaluated by the Member States, this would benefit the implementation of the integrated regulatory strategy conducted by ECHA.
- The administrative processes associated to dossier and substance evaluation and the time needed to generate information is taking a lot of time. An effort needs to be made to speed up the processes by: improving choices about whether to initiate dossier evaluation or substance evaluation; whether to run substance evaluation and compliance checks in parallel; whether to start substance evaluation in parallel to restrictions or authorisation.
- Dossier and substance evaluation processes are working but need to be improved so that they can deliver faster and better, and do not represent the bottleneck in the 'pipeline' of the integrated regulatory strategy. Over half of the registration dossiers have been found non-compliant, suggesting that industries have to generate further information.
- Modifications of individual steps in the formal evaluation procedure may also be considered to further improve its efficiency and effectiveness in particular with regard to the third party and the two-step registrant consultation, but also the roles of the Member State competent authorities and the MSC.
- With compliance checks limited to 5% of dossiers[40] and a comparatively even much smaller number of substance evaluations, the formal evaluation processes cannot be the main data-gap filling solution. The compliance check target linked to individual tonnage bands seems ineffectual in light of the evolution of the integrated regulatory strategy, the common screening which already now combs through all registrations and the possibility of addressing groups of substances. Therefore the compliance check target should be revised accordingly.
- In the longer-term, evaluation will need to move from successfully addressing dossier deficiencies and concerns of high volume substances (due to some specific endpoints such as carcinogenicity, reproductive toxicity), to the assessment and improvement of other endpoints. Evaluation should eventually reduce to monitoring the continuous

[39] The integrated regulatory strategy is further described in section 6.3.1.1 (internal coherence of REACH)

[40] The 5% target applies per tonnage band without time limit and it is multiannual by nature

compliance of all the dossiers in light of technological development and registration of new substances.

- Evaluation decisions are an important driver to generate new information; also in the recent decision of the European Ombudsman concerning the delay by the European Commission in processing files on reproductive toxicity of chemicals, the lack of incentives for registrants to spontaneously update their registration files despite their obligation is, together with the enforcement difficulties, have been identified as the main cause of the delay to generate new information.

5.6. Authorisation

Substances with specific hazard effects on human health and the environment can be identified as substances of very high concern (SVHCs)[41] and added in a Candidate List for possible inclusion in the Authorisation List (Annex XIV) and thus be subject to authorisation.

Manufacturers, importers or downstream users need to have an authorisation for the placing on the market or the use of a substance on the Authorisation List. Authorisations are granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. If not, an authorisation may still be granted if it is proven that the socio-economic benefits of using the substance outweigh the risk to human health or the environment and that there are no suitable alternative substances or technologies.

There is some evidence[42] that the objectives of authorisation are being achieved through the progressive substitution of SVHCs by suitable alternatives and the reduction of the risks through controlled use.

Key findings on the way in which substances of SVHCs are identified and added to the Candidate List, and subsequently prioritised and included in the Authorisation List (Annex XIV) include:

- The SVHC Roadmap is proving an effective tool[43] through setting out priority criteria and a methodology to ensure that, by 2020, all known relevant SVHCs are included in the Candidate List. It is improving regulatory coherence, transparency and predictability. For more information see annex 4 paragraph 6.1.2 and 6.2.
- The work under the SVHC Roadmap is progressing beyond expectations. More than 600 substances have been screened and for the relevant ones (159) a Regulatory Management Options Analysis[44] (RMOA) has been prepared. All the substances with

[41] Meeting criteria for classification as carcinogenic, mutagenic and toxic for reproduction 1a and 1b (CMR), persistent, bio accumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and other hazard substances such as endocrine disruptors raising an equivalent level of concern.

[42] Link to Study on the impacts of REACH authorisation - final report

[43] According to the public consultation conducted for REACH Evaluation, industry stakeholders perceive the implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), as a positive factor contributing to coherent implementation of authorisation and restriction under REACH.

[44] Originally the RMO stood for risk management options. To avoid confusion with the obligations under Article 69 to prepare an annex XV dossier when a risk has been identified and the obligation in Annex XV to determine the most appropriate Union wide measure to address the identified risk and to better reflect the actual work done, the RMO is now called Regulatory Management Options. Regulatory

confirmed SVHC properties have been assessed. Further work is on-going for 500 cases where data are being assessed or further information and data generation is needed before analysing the most appropriate regulatory action. The focus should now move to identifying new SVHCs, generating information on hazard properties and speeding up the process through addressing similar substances together in groups.

- Encouraging as many companies as possible to substitute SVHCs early enough so that they do not have to apply for authorisation at all is one of the main challenges in the implementation of REACH authorisation. Inclusion of substances in the Candidate List works as a driver for the companies concerned to look at the possibilities of substitution[45] (more information can be found in annex 4 paragraph 6.2)
- Between 2013 and 2017, 36 substances were included in the Candidate list, meaning that in total 174 substances were listed. The rate of inclusion has slowed down compared with the period of 2007-2012 where 138 substances were included in the candidate list. This is due to the fact that, since 2012, more complex cases, such as Persistent, Bioaccumulative and Toxic (PBT), very Persistent, very Bioaccumulative (vPvB) substances and substances of equivalent level of concern[46,] were screened out, requiring more detailed RMOAs and, in some cases, generation of new data.
- The Authorisation List (Annex XIV) contains 43 substances by June 2017, less than estimated in the baseline (approximately 120 substances by 2016[47]). As announced in the Commission REFIT Communication in 2014[48], the Commission has introduced some measures to improve the authorisation process and is considering further measures to improve the authorisation process and make it more predictable. These measures include reducing the frequency of amendments of the Authorisation list (done), simplifying the authorisation process for some specific low-risk cases (ongoing) and consideration of socio-economic impacts when including new substances in the Authorisation list (done).
- ECHA had received by March 2016 applications for authorisation for only 21 out of the 31 substances included in Annex XIV. This may be an indication that substitution is taking place for all or at least part of the remaining 10 substances. The authorisation process is leading to substitution even from the early point of inclusion in the candidate list.
- The implementation of the new authorisation application process has met numerous challenges; being a new process, the general working procedures still have significant

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Management Option (RMO) Assessment is the process for identifying the best regulatory option for a substance. The RMO Analysis is the document presenting the information on the substance, the possible options and the preferred one.

45 Survey of (CSES 2015 et al) found that about 20% companies responded to placing of a substance relevant for their business on candidate list by launching R&D to develop new substances and further 30% launched initiatives to find alternative formulations of existing substances

46 Meeting criteria set out in Article 57(f)

47 8 substances in 2011, then 12 added in 2012 and 25 per year thereafter as it was expected that the identification of substances of very high concerns would become easier due to a better knowledge of chemicals through the REACH processes

48 COM (2014) 368 " Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook"

margin for improvement. Although important efforts have been made such as in the case of use in low volume or in the case of use of legacy spare parts[49] by the Commission services to make the process clearer and simpler.

- There is still room for improvement in particular for applications submitted by upstream operators in the supply chain and a guidance document has been recently published on *How to apply to authorisation* to help companies to be more precise on the description of uses, on the representative exposure scenarios, on the socio-economic analysis.
- The costs of applying for authorisation remain high for individual companies, even though they have decreased (i.e. from EUR 230 000 on average per substance, use and applicant for the first applications in 2013 to EUR 120 000 in 2016). More details are included in the Annex 4, paragraph 6.7
- Recent efforts to clarify the required information for applications for a wide scope of uses or covering many different operators should be assessed as soon as sufficient evidence becomes available to see whether they have led to good quality applications. Such improvement will be key in making the process work efficiently, and will make it less controversial to subject new substances to authorisation in the future.
- When substitution is not possible, there is evidence that authorisation has led to an improvement in the risk management of SVHCs, reducing workers' exposure and emissions to the environment. This was proved by several applications for authorisation prepared by the companies. Companies are actively seeking to substitute and investing in substitution related activities.
- Feedback from applicants, the ECHA Committees, Member States and interested stakeholders will continue to be necessary for identifying and resolving remaining challenges. Ongoing activities such as Commission workshops and ECHA dialogues with the applicants will help to reinforce such improvement.
- As an example, for non-threshold substances applicants should describe the remaining risk quantitatively/semi-quantitatively assuring that the exposure levels are as low as technically and practically possible which then has to be assessed by RAC. This information on the remaining risk is an input to the socio-economic analysis of the applicant to be assessed by SEAC in order to consider if the benefits of continued use outweigh the health and environmental impact[50].
- In relation to the competitiveness and innovation of EU industry both negative effects (possible relocation and competitive disadvantage for EU industry as a result of imported articles not being subject to authorisation) and positive effects (development of alternatives) have been raised by industry. Those are further described in section 6.1.1.3. and annex 5 paragraph 2.4.2.

[49] uses of Annex XIV substances to produce legacy spare parts for certain articles (for example aircraft and motor vehicles) where the substance is required for repairing an article that is no longer produced after the sunset date

[50] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0814&from=EN

5.7. Restriction

Restrictions limit or ban the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article, including imports.

A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Union wide basis. ECHA can also propose a restriction on articles containing substances that are in the Authorisation list (Annex XIV). Anyone can comment on a proposal to restrict a substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

Since the 2013 REACH Review, new restrictions have been proposed but at a slower pace than expected. This seems to be driven by a number of factors including lack of information to identify good candidates, and a demanding process that puts Member States off from proposing restrictions. A number of efforts are being made to improve the efficiency of the process.

Key findings on the implementation of the restriction process include:

- During the period between January 2011 and December 2016, the Commission adopted 13 restrictions under Article 68(1). Overall, the number of restrictions initiated per year is about the same as in the final years of the pre-REACH system. This falls far short of expectations at the time of adoption of REACH of 11 restrictions per annum.
- A barrier to effectiveness is that it is difficult for Member States to find and invest resources in the preparation of Annex XV dossiers, which are demanding in terms of their technical/economic content. One Member State estimated the costs of preparing a proposal for restrictions under REACH to be between EUR 0.5 -1 million. Other barriers include high demands by the ECHA Committees during their opinion-making process.
- The evaluation has shown that EU companies are at a competitive disadvantage in relation to imported articles containing CMR substances because they are generally not used in the EU in consumer articles. In these cases, a restriction can be enacted to prevent the introduction of articles containing these CMR substances in the EU market via the simplified procedure envisaged in article 68(2)[51]. This would provide a level playing field between EU and non-EU companies. The competitive disadvantage of economic operators in EU should also be considered when introducing a restriction by advancing the start of the restriction process initiated by ECHA (see Annex 4 paragraph 7.3) for substances subject to authorisation and present in articles (Article 69(2)[52]).
- The efficiency of the REACH restriction process has so far not met original expectations, but it has been improved since 2013 on the basis of the recommendations of the Restriction Task Force[53] and of the enhanced cooperation of

[51] A restriction for consumer articles for CMR (categories 1A and 1B) substances listed in Annex XIV.

[52] The Agency shall prepare an annex XV dossier when a risk has not been adequately controlled for the use of the substance (listed in Annex XIV) in articles.

[53] The Restriction Task force is composed of members from Commission, ECHA, RAC and SEAC and Member States as Dossier submitters.

authorities (Commission services, ECHA and Member States eg through common screening and regulatory management option analysis) in the preparation of new proposals for restrictions. (Further information is provided in annex 4 paragraph 7.4.1).

- There is room for further improvement in the restriction process. The implementation of the recommendations of the Task Force is "work in progress". The activities will continue on the basis of experience gained in the preparation of Annex XV dossiers, ECHA should review the requirements for the conformity check and continue its efforts to obtain a maximum of information through the public consultation. RAC and SEAC should diligently scrutinise the information submitted in the dossier and via the public consultation, including in particular requests for exemptions. Finally, the Commission services intend to provide guidance to RAC and SEAC as to how to adopt opinions when, despite all efforts, information is lacking.

5.8. Member State activities other than enforcement

Every five years, Member States submit to the Commission a report on the operation of this Regulation in their respective territories. These Member State reports provide information on issues such as Competent Authorities activities, work of the helpdesks, and the Member State involvement in many of the different REACH activities (evaluations, restrictions, SVHC dossiers, etc.).

Member States authorities submitted reports on their activities in 2015 that had improved in terms of completeness and consistency compared to the 2010 reports. These reports provide part of the evidence base for this evaluation and the conclusions from the report include:

- There are 45 REACH Competent Authorities (CAs) operating in the 28 Member States and the 3 EEA countries. 6 Member States have more than one CA. Competent Authorities are generally satisfied with their technical expertise, while some consider their financial and human resources too limited to achieve all activities required under REACH.
- CAs generally expressed a high level of satisfaction with the cooperation between CAs at EU and national levels and with ECHA and the Commission. However, there are concerns about the resources available for fulfilling the REACH tasks.
- The Commission underlines the crucial role of Member States to support duty-holders and facilitate the fulfilment of their obligations by providing guidance through national helpdesks and awareness-raising activities. Two third of Member States have targeted SMEs for such activities. Most common awareness raising activities include the production of easily accessible information content, (leaflets and newsletter), organisation of seminars, development of websites and use of social media.
- The next version of the Member States' questionnaire will be re-evaluated with the view to being further streamlined.

5.9. Enforcement

The Member States, ECHA and the Commission all play a role in enforcement. The Member States have the legal powers to enforce against duty holders. However, REACH delegated some 'enforcement powers' to ECHA, for example, in the case of dossier evaluation. Moreover, ECHA hosts information (e. g. registration dossiers), which in case of non-compliance, needs enforcement action by Member States' enforcement authorities. The Commission's enforcement role is to check the proper application of REACH, making sure Member States and ECHA apply and enforce REACH.

To improve enforcement, new procedures and communication channels have been developed between Member States and ECHA in specific FORUM enforcement projects and also between Member States. Particularly relevant is the Forum for Exchange of Information on Enforcement (Forum), which is a network of authorities responsible for the enforcement of the REACH, CLP and PIC regulations.

Since the 2013 REACH Review, an effort has been made to improve enforcement and progress can be seen in a number of areas, but it is clear that enforcement is still weak in some aspects and in some Member States.

Key conclusions on enforcement include:

- The amount of work carried out by Member States authorities, progress towards common enforcement strategies and the increase of activities of the Forum have provided good results but improvements are needed.
- In response to the 2013 REACH Review, the Commission developed enforcement indicators in cooperation with Forum members. 50 enforcement indicators were proposed at three levels (EU, Forum and Member States)[54]. This is the first time that such an approach has been developed in the field of enforcement of chemicals legislation in the EU. It is still premature to draw final conclusions on the reliability of the first quantitative results of the indicators.
- The average level of REACH compliance[55] reported by the Member States and ECHA has varied from 79 % to 89 % in the period from 2007 to 2014[56]. In this period, the areas with lower level of compliance are the ones related to control of imports and supply chain obligations (e.g. 52% non-compliance for safety data sheets).
- The indicators show differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end). These findings may be influenced by substantial differences in enforcement culture between Member States.

[54] Enforcement indicators for REACH and CLP within http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280

[55] The average level of compliance is calculated annually as the median value of the average levels of compliance reported by Member States. The average level of compliance experienced at MS levels take into account all controls carried out to REACH duties holders specific year.

[56] Information provided in accordance with Article 117.1 of REACH on Member States reporting obligations

- Enforcement activities are complex since they are carried out at different levels. The Member States have the main role in enforcing the Regulation but ECHA, and in particular the Forum, play important roles by supporting enforcement activities in small Member States.
- Enforcement activities have increased over time: Member States are now reporting close to 100 000 controls per year, and there is some prioritisation of these (eg reflecting risks). Member States should carry out further activities in order to increase the harmonisation of enforcement across the EU as also requested by industry during the public consultation (more information in annex 4 paragraph 9.2). REACH is of direct application in all Member States and further implementation efforts are needed to create a level playing field among Member States and all the actors involved in particular from those Member States which are not particularly active in the enforcement projects developed by the Forum.
- The result of the open public consultation shows that there is negative perception with regard to the question if REACH is uniformly enforced across the EU[57]. Stakeholders identified particular shortcomings with regard to imported goods. Mostly businesses and industry organisations stated that Member States should significantly increase controls in this area. This was seen of such importance because the lack of controls puts at risk Member States' enterprises competitiveness in a globalised trade system.
- The effectiveness of national enforcement activities could be further improved (e.g. in the areas of safety data sheets and imported goods), and also needs to be better communicated (e.g. by publishing Member State level enforcement indicators, developing and communicating national enforcement strategies and broadening national capabilities).
- The Commission services, the Forum and the Member States should further refine the enforcement indicators in the light of experience gained with their implementation. This system allows progress to be monitored (e.g. comparing different years) to better inform enforcement authorities, duty holders and the public in general.

5.10. Fees and charges

ECHA undertakes work related to REACH and other chemicals legislation (CLP, Biocides, etc). For REACH, it receives income from fees and charges for work that ECHA does on registration and authorisation. This income covers only part of the costs of the services provided by ECHA, and so there is a balancing EU subsidy.

Key findings include:

- The fees and charges revenue was foreseen to amount to EUR 510 million over the period 2007-2016 and the total REACH budget over the same period to EUR 757 million (implying a balancing subsidy of around EUR 247 million).

[57] 70% of the respondents said that REACH is not uniformly enforced. Such negative views were predominantly expressed by businesses (most of the respondents), but also by NGOs and consumer organisations.

- Revenue has been higher than expected, which has had an impact on the level of the EU subsidy. In practice, the fees and charges revenue over the period 2007-2016 was EUR 581 million (14% higher than expected) and the EU balancing subsidy was EUR 225 million for this period.
- The amount of fees and charges collected allowed ECHA to be self-financed for the period 2013-2015. Income from registration will be significantly less for the upcoming period (as all 'old' chemicals have been registered now, and only new ones will incur fees). From 2016 on, a significant EU contribution is needed to balance ECHA's budget.
- Half of the registrations over 2013-2016 relate to substances produced outside the EU.
- In line with the conclusions of the 2013 REACH Review, the Commission introduced in March 2013 fee reductions in favour of small and medium enterprises (SMEs) for both registration and authorisation; the reduction reaches up to 95% for micro-enterprises. For the period 2013-2016 the additional total fee reduction for SMEs represented a total amount of EUR 1.7 million.
- Stakeholders generally perceive registration fees and charges as adequate, but for authorisation they are generally considered too high. The Commission services are considering the possibility to abolish the additional fee per applicant in a joint application and increase the fee (to 90% of the base fee) for each additional use of a substance. This should contribute to reduce significantly the authorisation costs since companies will have an incentive to introduce joint applications.

6. ANSWERS TO THE EVALUATION QUESTIONS

6.1. Effectiveness

6.1.1. TO WHAT EXTENT DOES REACH MEET ITS OBJECTIVES?

The evaluation of effectiveness looks at the extent to which REACH fulfils the objectives it is meant to achieve. Based on the intervention logic, the main objectives are:

1) to achieve a high level of protection of human health and the environment
2) to promote alternative methods for assessment of hazards of substances
3) to achieve the free circulation of substances in the internal market
4) while enhancing competitiveness and innovation

Assessment question: "To what extent does REACH meet its objectives?"

Progress has been made towards the REACH objectives.

The impact on protection of human health and the environment will take a number of years to become visible. However, evidence indicates that the outcomes defined in the intervention logic are being delivered in line with expectations. Information on substances is generated, passed to some extent along the supply chain and used to better assess and manage chemical risks, implying that REACH is being effective in terms of protecting human health and the environment to some extent.

The development and consideration of alternative methods have greatly improved during the last ten years, although this may have been at the expense of delivering (hazard)

information. In fact, alternative methods are not yet available for high-tier endpoints but registrants tended to avoid animal testing.

Regarding the free circulation of substances on the internal market, it can be concluded that REACH is delivering towards this objective. No clear effects are seen on the competitiveness and innovation as those depend on other more important factors that influence the market.

What is the issue?

The Intervention Logic sets out the sequencing from actions to outputs to outcomes to impacts, with the impacts relating directly to the objectives of the legislation. This question considers the degree to which the objectives are being met through an assessment of how effective the different actions envisaged in the intervention logic are proving. As such, answering the question leans heavily on the state of implementation as discussed in Section 5, considering also details set out in Annexes 4 and 5. However, the answer stops short of an assessment of the costs and benefits, which is instead considered under the efficiency questions.

6.1.1.1. Protection of human health and environment

The high level of protection of human health and the environment can be reached via improved knowledge on substances and their uses and properties as such knowledge allows reducing risks through improved risk management measures. This requires registration and evaluation to work well. This in turn can result in improved risk management measures through the passing of information along the supply chain and the operation of the restrictions and authorisation processes. This section looks first at the evidence on the effectiveness of the actions as indicated in the intervention logic, and then at the evidence on the end impacts.

6.1.1.1.1. Availability of information on substance properties and uses

The results of the 10-year update of the REACH baseline study show that 81% of the registered chemicals have a Chemical Safety Report[58] and most (75%) of those contain worker exposure information; this is a clear increase in the availability of data compared to 2012 and especially 2007. Given that the baseline for the study was the situation before REACH, it suggests as a result of REACH, there has been progress in the generation of information on chemical substances and significant progress on making available information on chemical substances. This has led to a constant increase in the number of hazardous substances identified, controlled, restricted or substituted. Exposure limits (Derived No-Effect Levels (DNELs)) are available for more substances compared with the pre-REACH situation. This means more and better data are available to perform chemical risk assessments[59].

REACH has also enhanced the knowledge within companies on the properties and uses of the chemicals including the exposure of substances to human health and the release to the environment. Companies also reported that the data base on substances under REACH has improved and classification is regarded as more trustworthy.

[58] For the remaining dossiers, Chemical Safety Report is not legally required

[59] The increased availability of information on chemical substances is identified by the REACH Baseline Study – 10 years' update linked to registration.

In addition, communication throughout the supply chain has increased and more information is available to chemical suppliers about the uses by downstream users. Nonetheless, there are still important gaps in the information passed down and an important share of downstream users still remain unaware of their REACH obligations. This is notably the case for article suppliers that have problems in obtaining and monitoring information on SVHC in their articles.

In spite of these positive trends, REACH has not yet produced the amount of new information on chemicals that was expected when REACH was adopted, in particular concerning the long term endpoints. As an example, the number of new studies generated and submitted [by registrants] since REACH entered into force is less than originally predicted (for further details see table 4.1 on number of tests per end point in Annex 4 paragraph 1.5). This means that less new hazard information than expected has been generated to enable identification of substances of very high concern.

The registration process has been generally effective and 95% of all registrations have been submitted as joint registrations. This shows that the infrastructure built by industry to share information and develop joint dossiers has worked. Non-compliance on at least one information requirement has been identified in at least 63% of the dossiers checked for compliance over the 2009-2016 period. This seems a high fraction but it has to be understood within its context in order to assess the real impact on the effectiveness. Deficient dossiers do contain useful information, as those deficiencies only include gaps not necessarily related to toxicology or exposure (e.g. substance identity) and double-counting cannot be excluded.

In order to improve the safety of chemicals ECHA has issued an integrated regulatory strategy which came into effect in 2015 by launching a common screening approach for all substances and registration dossier. This strategy focuses mainly on substances manufactured or imported in high volume and having a potential exposure/emission, which are prioritised for further risk management measures, such as substances evaluation, listing as very high concerns substances, restrictions, classification and labelling). This would enhance further the good functioning of other REACH processes and controlling the safety of chemicals of concern.

While REACH is able to address emerging issues such as the risks from nanoforms of substances, the lack of specific information about nanoforms covered by REACH registration dossiers remains an issue. Several compliance check decisions by ECHA on the registrations of substances with nanoforms have been appealed to the Board of Appeal, and four were annulled. The Commission has addressed these shortcomings through the recently proposed amendments of various REACH Annexes to clarify the information requirements for the registration of nanoforms. Some scientific gaps remain as to the suitability of test methods for nanoforms of substances and these are addressed in the OECD test guidelines programme.

Overall, update of registration dossiers and subsequent evaluation is a time-consuming process, as it, when data needs to be provided by the registrant, normally takes two to four years from the date of the decision.
Therefore, although it is too early to appreciate the overall impact of substance evaluation on risk management, a significant impact is anticipated in the coming years.

Shifting the burden of proof to industry

An important driver of the generation of information under REACH was the shift in the burden of proof to industry mainly through the registration and authorisation processes.

However, REACH does not eliminate the necessity of authorities to justify when they require action under REACH. The evaluation, restrictions and authorisation actions are designed to enable authorities to justify action in an easier and more efficient way than in the past.

The output of the registration process (more than 65 000 registration dossiers for some 17 000 substances) illustrates that industry has adhered to this shift in the burden of proof and taken up their legal obligations by submitting registration dossiers. Although this brings in additional costs for industry[60], it also results in a comprehensive data generation and assessment system for the main chemicals manufactured, imported and used in the EU, delivering an unprecedented amount of information compared to the pre-REACH system and to other regulatory systems[61] and enabling companies to better control the risks of all their registered chemicals by introducing appropriate and target risk management measures compared to the pre-REACH system..

However, the identified non-compliance of registration dossiers shows that although the burden of proof is on industry, the information provided is often not sufficient for authorities to identify and prioritise the need for action. In addition to the actions envisaged in REACH, ECHA and Member States invest resources to get the additional information from other sources, causing delays and returning to the 'pre-REACH' system where the full burden of proof was on authorities.

The REACH conference hosted by the Dutch presidency emphasised[62] the importance for companies – instead of governments – to demonstrate that the chemicals they place on the market can be used safely, by providing and updating information in the registration dossiers[63]. It was considered that real proactive ownership on the part of industry should be encouraged so that they view REACH as a working instrument rather than just a one-off obligation.

6.1.1.1.2. Reduction of risks

The development of risk is monitored by a Risk & Quality Indicator system consisting of an element assessing the nominal risk and an element assessing the quality of the underlying data. The resulting Risk Scores and Quality Scores are calculated for four impact areas: workers, environment, consumers and human health via the environment. (more information is given in Annex 5 paragraph 1.5)

A positive trend is observed from monitoring risk scores[64] which show a clear improvement[65]. The trend was already evident in the five-year update and is now observed for a larger dataset, related to the substances registered so far.

More proactive risk management activities have been introduced in companies as a result

[60] Costs are further analysed in section 6.2 on efficiency of REACH and Annex 5 on horizontal issues

[61] This is further developed in section 6.1.2 on other effects of REACH

[62] Information note from the Presidency to the Council on the policy conference "REACH forward"

[63] Information on toxicological properties, uses, exposure and risk management measures

[64] Risk Characterisation Rations and Risk Scores established according to the methodology developed for the Baseline study and calculated at different points in time to monitor risk reduction. See the Report of the REACH baseline study: 10 years update

[65] From the REACH Baseline Study – 10 years' update

of REACH, leading to improved risk management procedures and improving communication in the supply chain. Some of the companies involved in applications for authorisation confirmed that they improved their risk management measures at the workplace ²when preparing their applications. As a result of new information received through safety data sheets from companies submitting applications for authorisation, users of authorised substance usually improve their risk management measures[6667].

However, there is still limited awareness about REACH requirements (in particular among downstream users) and the appropriateness of information for risk management passed along the supply chain could be further improved (i.e. SDS), especially among SMEs, as indicated by the relatively high level non-compliance (52%) related to the communication of information in the supply chain that has been observed through enforcement actions (more information in annex 4 paragraph 9.1.1). Information received with extended SDS in some cases leads to improvement of risk management measures[68]. However, limited awareness may result in risk reduction measures not being applied by downstream users.

Risk reduction results from risk management measures applied through the different REACH processes:

- Registration provides information on a substance (hazard, exposure) and appropriate risk management measures identified in the chemical safety assessment and safety data sheets .
- Evaluation refines the information identifying some properties linked to the hazard and exposure.
- Authorisation reduces risks of Substances of Very High Concern by encouraging their substitution by safer suitable alternatives and by ensuring risk control for specific uses.
- Restriction reduces identified uncontrolled risks through appropriate risk management measures and operational conditions during the manufacture and use of a substance.

The progressive restriction of use and banning substances and groups of substances of very high concern as a result of REACH should lead to lowering the human and environmental exposure to these substances and groups of substances. The evaluation and compliance check procedure is playing a major role in the identification of dangerous substances.

The number of restrictions (19 in 5 years) enacted under REACH is comparable to the situation pre-REACH (16 in 5 years). This falls short of what was expected from REACH at the time of adoption, on the basis of the Commission estimates that Member States would prepare 11[69] Annex XV dossiers for restriction per year, particularly given

[66] Study monitoring the impacts of REACH on competitiveness, innovation and SMEs – CSES, 2015, page 72

[67] The ongoing study on the effects of authorisation provides similar indications.

[68] Study monitoring the impacts of REACH on competitiveness, innovation and SMEs – CSES, 2015, page 73

[69] Estimation made by the Commission services during the drafting of the proposal for the REACH Regulation and discussed with Member States in the so-called Commission Working Group to prepare for REACH (2005-2006). These estimations formed the basis of the financial Fiche accompanying the

that more information would be available. However, this number provides only a limited indication of the effectiveness of REACH, as the REACH information requirements for technical dossiers to start a REACH restriction process are more complete than in the pre-REACH system. One of the difficulties compared to the pre-REACH system, in which the restriction proposal and the socio-economic analysis were developed by the Commission, is that under REACH the Member States have to prepare a restriction proposal within a much shorter timeframe (1 year versus up to 10 years).

Application of the precautionary principle to reduce risks

The precautionary principle is one of the three principles guiding environment policy under the Treaty. As stated in Article 1(3), the precautionary principle underpins REACH and its implementation. The Commission Communication on the precautionary principle[70] sets out the mechanism used by the Commission, and by analogy Union agencies, for the implementation of the precautionary principle. This mechanism when applied to REACH in effect has two steps:

(1) a scientific step, where the responsible scientific body (ECHA) assesses if the uncertainties are bigger than normal and if the consequences of those uncertainties could lead to a significant undesirable impact;
(2) a risk management step, where the responsible risk management body (the Commission and REACH Committee) decide what action, if any, is required.

The assessment set out in the scientific step was routinely applied under the previous legislation (existing substances). Under REACH, step 1 has been assessed by the scientific committee leading to two cases where the bigger than normal uncertainties were identified but no further risk management steps were taken on the basis of the Precautionary Principle. In two cases a decision was taken to generate further information[71].

Since the entry into force of REACH, the Commission has not proposed measures where action was based on the precautionary principle as ECHA opinions have not triggered such principle. In most cases, the ECHA and its Committees did not assess the scientific uncertainties to enable the Commission to consider possible action based on the Precautionary Principle.

The principle could be invoked by ECHA in cases where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question. In such cases, ECHA should highlight to the Commission which information is needed to clarify the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction. The restriction task force has identified this issue and recently the Committee assessment on uncertainties has been conducted.

Commission Proposal and the Extended Impact Assessment. The assumption for restrictions was that better information in the registration dossiers, more information on the hazard properties of substances (e.g. through substance evaluation), the ability to target the risk assessment and strict deadlines would significantly increase both efficiency and the ability to identify substances needing restrictions.

[70] The Precautionary Principle is enshrined in the Treaty on the Functioning of the EU and its definition and scope are set out in the Commission communication (COM(2000) 1final)

[71] Bisphenol-A (more information where requested on the alternative Bisphenol-S (same risk profile)), and D4/D5 (more information was requested on products similar to the ones restricted).

Substitution and risk reduction of substances of very high concern (SVHC)

Increased obligations on SVHC through the candidate listing[72] and authorisation provisions are leading to some substitution of those substances along the supply chain. Substances have been dropped from the market or not registered due to their properties (*good withdrawal*). The authorisation process is leading to the substitution of SVHCs at all stages[73] as a result of the substances being listed on the candidate list and in ECHA's recommendation of priority substances to be included in Annex XIV, as well as the actual listing of substances in Annex XIV.

Applications for authorisation were made for 23 substances out of the 31 subject to authorisation in March 2016, which is an indication that some substitution has taken place, although it is difficult to distinguish to which extent REACH has been the driver for that (See further details in annex 4 paragraph 6.5 and in annex 5 paragraph 1.8). Many of the applications for authorisation that have been assessed requested the time necessary to substitute the SVHC with a safer alternative[74] and seem directly related to the effect of REACH authorisation.

Overall, there is some evidence that the objectives of authorisation are being achieved. The SVHC Roadmap is proving an effective tool and work at this stage is progressing as expected in terms of effectiveness.

An additional issue to consider is the effect of delays in the adoption of restrictions of substances of very high concern subject to authorisation[75], when present in articles placed on the EU market. In particular, the delay in the adoption of restrictions for imported articles containing those substances after the sunset date could affect negatively the level of protection of human health and environment as well as create a competitive disadvantage for EU producers of articles.

Substances with endocrine disrupting properties

The potential for Endocrine Disrupting (ED) properties is one of several factors in the prioritisation of substances in ECHA's common screening approach, in evaluation and the implementation of the SVHC Roadmap to 2020. REACH has routinely been able to identify substances as having ED properties: to date, seven (groups) of substances have been added to the Candidate List using the WHO/IPCS definition when sufficient data exists on adverse effects, the underlying mechanisms of action and the causal relationship between the two. The criteria for the determination of substances with ED properties under the Biocidal Products (BP) Regulation will become applicable in June 2018[76] and it is expected that the criteria under the Plant Protection Products (PPP) Regulation will become applicable in November 2018. Those criteria are based on the WHO/IPCS

[72] Link to Candidate List of Substances of Very High Concern for Authorisation - ECHA

[73] Report on operation of REACH and CLP, ECHA, 2016, page 92

[74] About a quarter of the opinions have concerned "bridging" applications, where the applicant has identified its substitution strategy and applied for a specific period identifying when the substitution would take place[74.] (ECHA, 2016c p. 93).

[75] According to Article 69(2)

[76] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (Text with EEA relevance) C/2017/5467, OJ L 301, 17.11.2017, p. 1–5

definition. Also the joint scientific guidance of EFSA and ECHA for the identification of EDs will be established in 2018. The data requirements in the PPP and BP Regulations will be adapted accordingly in order to be able to assess whether the criteria are met. As the data requirements in the PPP and BP Regulations differ from the REACH data requirements, and the level of protection foreseen in the REACH legislation should be safeguarded, the applicability of the criteria to identify ED properties under the PPP and BP Regulations needs to be evaluated. This further emphasises the need to have effective testing methods available. Whilst the REACH standard information requirements have limited capacity for providing data on ED properties, a number of adverse effects related to ED mode of actions (human health and environmental) can be identified by the extended one-generation reproduction toxicity study (EOGRTS), as well as by some of the other information requirements[77]. Further details are described under the relevance questions (Part 7.4).

6.1.1.1.3. Impact on the incidence of diseases

The section above has shown that the steps of the intervention to a great extent take place as envisaged in the intervention logic, suggesting effectiveness for this objective. This should (eventually) lead to a positive impact reducing diseases and environmental damage. However, providing evidence on the impact is challenging because the main expected impact is the absence of certain adverse effects, and furthermore:

- the majority of impacts will materialise in the future, for example, because of latency periods;
- even if changes in incidence (such as rates of cancer cases) can be observed, it is difficult to attribute these changes to different drivers/interventions.

In terms of the expected impacts, the *Extended Impact Assessment* prepared during the adoption process of the REACH Regulation describes some of the potential health benefits of REACH resulting from health benefits for workers through reduced occupational exposure, effects of restrictions on the reduction of the risks to the environment and the general public. The health benefits were expected to be in the order of magnitude of EUR 50 billion over the next 30 years (in net present value terms)[78], assumed to start to occur 10 years after REACH implementation begins, and persist for another 20 years.

At present, a lot of challenges and knowledge gaps remain to assess the impact of REACH on health and environment (e.g. impacts on diseases). However, even the limited available information suggests that REACH has had a positive impact on health and the environment (e.g. human health benefits as a result of the enacted restrictions).

So far, information on changes in health resulting from a decrease in exposure to chemicals is only available for occupational skin diseases and occupational asthma[79]. A

[77] Effects related to human health for repeated dose toxicity, carcinogenicity and reproductive toxicity (e.g. according to OECD TG 421, OECD TG 422, OECD TG 414, OECD TG 408)77, while additional data on ED adverse effects related to environmental endpoints are gathered via tests on short and long term toxicity

[78] Based on the assumption that on average 10 DALYs are equivalent to 1 life saved, then 45 000 Disability-Adjusted Life Years (DALYs) would be equivalent to 4 500 lives saved per year due to REACH.

[79] RPA study - Information used in the RPA study was coming from two national OSH databases (the UK Health and Safety Executive and the German Social Accident Insurance).

progressive reduction in the occurrence of occupational skin diseases and occupational asthma has been observed, resulting in total cost savings of, respectively, around EUR 1.59-1.87 billion and EUR 249.9 million, respectively for the period 2004-2013. The trends observed are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some skin and respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes. Nevertheless, REACH is a factor for many of these aspects and so seems to have played a major role in reducing the number of cases of occupational skin diseases and occupational asthma.

ECHA has also assessed the expected annual human health related benefits[80] from restrictions processed under REACH since 2009 indicating also positive impacts for at least 81,000 consumers and workers, the value of which could not be estimated. An example with direct effects on consumers is the restriction of chromium (VI) in leather articles that applies since May 2015, which has been estimated to enable approximately 1.3 million people with chromium allergy to use leather articles without fear of symptoms and to avoid approximately 10 800 new cases of chromium allergy in the Union each year. The benefits, in terms of avoided healthcare costs, productivity losses (due to lost working hours) and avoided suffering (the willingness to pay for avoided allergy and symptom days) amounts to an estimated EUR 350 million per year.

6.1.1.2. Promotion of alternative methods

The available information, though limited, suggests that REACH enhanced the development, use and acceptability of alternative methods to replace, reduce, refine animal testing (see details in annex 4 paragraph 2.1.2.1).

In particular, there was a replacement of in vivo tests with validated and internationally accepted in vitro tests in the standard information requirements of REACH or in other cases the refinement of in vivo tests to reduce the number of test animals or improve data adequacy for classification and risk assessment (see Annex 4 chapter data sharing, test methods and avoid unnecessary animal testing).

For practical reasons e.g. lengthy administrative procedures of adoptions of the test methods regulation as well as inclusion of new OECD methods in the REACH Annexes, the uptake of alternative methods coming from OECD is taking considerable time and sometimes leads to discrepancies due to ongoing developments between the test methods regulation and the OECD guidelines, which may have evolved in the meantime.

For skin sensitisation the introduction of the first Adverse Outcome Pathway[81]-based test (alternative) approach has proven challenging, due to the inherent flexibility of the approach, which affects e.g. industry confidence as well as enforcement from Member States. Also in the alternative higher tier testing for reproduction toxicity the inherent flexibility has proven challenging. Reflections are necessary how in future such (flexible) approaches, which are expected to increasingly emerge in the near future, can be accommodated in the framework of REACH information requirements.

[80] Cost and benefit assessment in the REACH restriction dossiers, ECHA, April 2016

[81] A structured representation of biological events leading to adverse effects relevant for risk assessment

Because of the strong emphasis in the REACH text on the use of alternatives and the "last resort principle", REACH, together with the Cosmetics Regulation, is one of the principle drivers in the EU for the use of alternatives to animal testing[82].

Many registrants rigorously implement the legal requirements to propose testing on animals only as a last resort. However, a significant number of recently conducted in-vivo tests are still being submitted. The reasons for this need to be further explored; one could be the non-acceptance of alternative methods in Third Countries.

Positively, alternative approaches like read-across and weight of evidence are being used to a large extent to avoid or limit the need for (any) new testing (more information in Annex 4 paragraphs 2.1.2.1., 2.1.2.3.and 2.1.2.5). However, the scientific validity of such approaches needs to be better substantiated in many of those dossiers.

ECHA concludes in its third report on the use of non-animal test methods[83] that registrants generally made extensive use of existing information and adaptation possibilities before conducting new studies or proposing new high tier vertebrate animal tests, whereas regulatory requirements are updated to take up new reduction and replacement methods. The uptake and regulatory acceptability of the new methods in the EU also heavily stimulates validation and acceptance of alternatives in different jurisdictions.

Available information suggests that REACH enhanced the development, use and acceptability of alternative methods to replace, reduce, refine animal testing, but there are still areas of improvements regarding the use of adequate alternative methods. ECHA, which is putting a lot of effort into promoting new test methods through, among others, the update of guidelines on test methods stresses that the recognition of an alternative method by amendments under REACH and the Test Method Regulation[84] takes considerable time. However, formal recognition of new testing methods through inclusion in the Test Method Regulation remains a challenge due to the inherent administrative processes and the time required for translation of the long and highly technical test protocols in all EU languages.

The experience from recent modifications of standard information requirements in Annexes VII-X to REACH have also highlighted a number of challenges for regulatory acceptance of new methods. This can significantly influence the time needed to complete the process of gaining acceptance, in particular related to concerns raised in relation to assessing the equivalence of information generated via in vitro or in vivo testing, maintaining the previous level of protection for human health and the environment, addressing flexibility in test guidelines as well as testing costs and availability of test laboratories able to perform new tests.

6.1.1.2.1. Avoidance of unnecessary testing

Regarding data sharing, ECHA built a publicly accessible database of available data on substances registered under REACH, encouraging data sharing and avoidance of unnecessary duplication of tests. These effects are reaching beyond the EU as the information available through this database is being used in other jurisdictions.

[82] The interplay between REACH and the Cosmetics Regulation is further analysed in section 6.3.2.3

[83] Report on the operation of REACH and CLP, European Chemicals Agency (ECHA), 2016

[84] Commission Regulation (EC) No 440/2008

In addition, since 26 January 2016, it is no longer possible to submit an individual registration for a substance where a joint submission exists (95% of all registrations were joint registrations). However, some 700 previously existing individual registrations including notified substances and intermediates are still in breach of the joint submission obligation. Further data sharing could be enhanced by accommodating data sharing for structurally similar substances to allow better read-across.

Overall, effort has gone into the development and promotion of alternative methods. This is reducing the need for animal testing, but this may have been at the expense of delivering (hazard) information as for high-tier endpoints, alternative methods are not yet available and registrants have applied data waivers, adaptations or submitted testing proposals.

Until 31 December 2016, ECHA has taken decisions on 953 testing proposals, some of which concerned several studies that are already being or will be performed. 467 of the 953 testing proposals concerned prenatal developmental toxicity and 359 concerned repeated dose toxicity. 183 testing proposal decisions on reproductive toxicity are being finalised by the Commission. On the one hand this means that less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted either. Where no new data has been generated, the dossiers either contain data waivers or adaptations.

The cost of data sharing seems to affect SMEs considerably, as data sharing negotiations take a long time, putting time pressure on new registrants and reducing possibilities to place the substance on the market.

6.1.1.3. Internal market, competitiveness and innovation

The changes in the internal market, competitiveness and innovation are all linked, and can be especially felt by SMEs. Strengthening the internal market through harmonisation allows for a more level playing field, lowers costs for businesses and allows for greater economies of scale. A stronger internal market is one of the positive factors for competitiveness, but REACH can also hinder competitiveness, for example, through increased costs for businesses. At the same time, REACH can affect the incentives to innovate, which in the long term underpins the chemical sector's competitiveness.

At the time of adoption, there were no quantified expectations with regards to competitiveness.

6.1.1.3.1. Free circulation of substances in the internal market

The REACH Regulation has among its objectives to ensure the free circulation of substances on the internal market through harmonisation and reduction of the barriers for intra-EU trade.

Europe has a large and integrated market made up of a customer base of over 500 million consumers and with chemicals sales worth EUR 519 billion in 2015[85]. The importance of the internal market for chemicals is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports'[86]. There has been a continuous increase in the intra-EU trade of chemicals over the last decade, strengthened by the removal of trade and non-trade barriers within the EU and the enlargements of the European Union

[85] CEFIC, chemdata international, 2015

[86] European Chemical Industry Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017

in 2004 and 2007. Intra-EU sales increased from EUR 197.2 billion in 2005 to EUR 282.3 billion in 2015 – a 43.2 % increase during the last 10 years. How much this increase can be attributed to REACH is not certain, but these figures suggest that REACH is contributing to achieving the internal market.

Companies from the chemicals sector, as well as with their downstream users[87], report no effects (neither negative, nor positive) on the trade of chemical substances within the EU/EEA due to the implementation of the REACH Regulation. While no discernible impact of REACH was identified, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European chemicals legislation / integration of the Single Market. They also flagged the need for further efforts to make market surveillance and enforcement practices more aligned (see 7.1.3.2 for more detail) across the Member States by, among others, approaching the inspections and the relative resources (quantity and quality) allocated to ensuring compliance with REACH[88].

ECHA also recommended that to achieve a fair level-playing field throughout the single market, all Member States should consistently enforce ECHA and Commission decisions in their territory (this issue is further discussed in chapter 7.1.3.2.).

6.1.1.3.2. Competitiveness

Trends for the EU and global markets

As described above, intra-EU trade of chemicals has increased over the last decade, while the total EU chemicals sales remained relatively stable, though with some fluctuations. Moreover, as a result of a solid recovery from the aftermath of the economic crisis in 2008, the extra-EU trade balance showed clear signs of recovery, reaching over EUR 40 billion in 2015. This means that domestic (home) sales have decreased while the increase in intra EU exports combined with an increase in exports to non-EU countries has led to an increase of the total chemicals sales over the period 2005-2015 (from EUR 458 billion to EUR 519 billion)[89].

At the same time, the share of the EU industry on the global market has been decreasing over the past 20 years[90]. It is not possible to say if REACH has contributed to this change given the global trends in play such as cheap energy in the US, China's economic boom and hence increase in domestic demand for chemicals.

Market effects observed in relation to REACH

The costs of specific REACH processes are presented in detail in Annex 5. However, some positive and negative effects can be observed. The effects of registration on competitiveness seem broadly in line with the expectations (as discussed in detail in Annex 5, paragraph 2.4.2), although concerns about the vulnerability of some specific sub-sectors (e.g. essential oils, textile dyes) and SMEs remain. ECHA, the Commission and Member States are providing specific support to mitigate those concerns in preparation for the 2018 registration deadline.

[87] A large majority (80-85%) of respondents to a business survey conducted by CSES in the context of the study Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES et al, commissioned by the European Commission, 2015

[88] Further analysis in Annex 4- enforcement section

[89] CEFIC, Chemdata international 2015

[90] The share of the EU in world sales was 32% in 1995 and 15% in 2015.

Registration costs are claimed also to be the main driver for some substance withdrawals observed[91]. Around half of the registrations with ECHA have been for substances not produced in the EU (50% over the 2008-2016 period, 40% in 2016).

Downstream users have also expressed concerns about the control of SVHCs through the authorisation process, perceived as a competitive disadvantage vis-a-vis companies from third countries, or the information requirements for SVHCs in articles[92].

Compliance with REACH affect SMEs more significantly than larger companies[93] and SMEs perceive the benefits of the Regulation to a much lesser extent[94]. Some concerns were expressed by industry about increases in the cost base of companies, which may force smaller firms out of the market or inhibit the entry of new ones, thereby reducing the industry's overall supplier base[95].

As anticipated in the extended Impact Assessment conducted in the preparation of the REACH Regulation some market consolidation seems to have occurred due to decision of manufacturers/importers to remove some of their substances from their portfolio. However, this seems to have been done after consideration of the cost of registering, the profitability of the chemicals and the availability of adequate substitutes. Therefore, despite the effect on individual companies, there is no evidence of any major negative impact at EU scale resulting from the non-availability of substances.

6.1.1.3.3. Innovation behaviour

Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on Research & Development (R&D) and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting R&D resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and the higher transparency enable the users of chemicals to make better choices in the design of products and in their use.

Further details and evidence underpinning this analysis is developed in Annex 5, paragraph 2.4.2)

R&D and general innovation drivers

The 'Porter hypothesis' states that stricter environmental legislative requirements may encourage companies to increase spending on research programmes, thus acting as a trigger for innovation towards sustainability, which may provide first movers with competitive advantages[96]. However, effects of the REACH processes on innovation are

[91] Study on Monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al): Near to one third of companies (including downstream users) having reported to be affected by a withdrawal of a substance from the market due to registration cost

[92] Similar views have been gathered through the online-public consultation, where industry respondents were rather negative about the achievement of the competitiveness and innovation objective.

[93] Study *Monitoring the impacts of REACH on innovation, competitiveness and SME*s, page 101 onwards

[94] SME panel

[95] Similar views have been gathered through the online public consultation and the SME panel.

[96] As acknowledged by WWF, 2003, CIEL, 2013, OECD, 2014 and ChemSec 2016 (add link to the bigger picture)

CIEL (2013) notes that the implementation of stricter measures with REACH has enabled significantly increased patenting of alternatives by major chemical manufacturers. Chemsec (2016) reports that chemicals and chemicals-

complex and different companies perceive the impact of REACH on their capacity to innovate differently[97].

On the one hand, the costs incurred by companies in implementing the Regulation may detract from the resources from R&D and innovation activities[98]. On the other hand, the implementation of REACH has also led to an increase in R&D activity[99] [100].

The improved communication (upstream and downstream) in the supply chain should logically be providing potential for more innovation, business development opportunities and more efficient and effective supply chain management practices. However, those effects could not be quantified. Furthermore, improved availability of information and transparency can help downstream users to make better informed choices when developing new or applying existing products, hence increasing their ability to innovate.

Companies on the one hand capitalise on the information and knowledge generated as part of the registration process by e.g. launching new products or services. On the other hand, companies that experienced a withdrawal from the market may have been negatively affected or they may have responded with R&D activity to identify alternative substances.

Authorisation also affects the innovation activity as the inclusion of substances into the candidate list and the authorisation list works as a driver for research to find alternative substances or technologies. However some industry stakeholders highlighted that the authorisation process is slowing down the product development and diverting resources from innovation that would improve competitiveness. Other expressed the view that the candidate list and other instruments[101] is increasing the transparency and providing guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.

Innovation and substitution

A positive trend can be observed concerning innovation and substitution[102] as there is the general tendency to change the product range to replace hazardous substances. REACH encourages substitution by safer substances but it is difficult to attribute substitution

related legislation triggers investment in R&D and leads to innovation on a number of fronts including chemical substitution, improved manufacturing processes, product design, etc. And in some cases these innovations confer a first mover competitive advantage to the EU-based manufacturer both in domestic as well as international markets.

[97] The business survey conducted in the context of the study monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al, 2015) suggests that, for some companies, REACH does not seem to provide any major incentive for innovation, in the sense of improving their competitiveness in comparison to non-EU competitors. 35% of respondents perceive a negative impact of REACH on their capacity to innovate, whilst 11% who perceive a positive impact and 54% did not see REACH having a notable effect, either way, on their innovation activities.

[98] Study Monitoring the impacts of REACH on innovation, competitiveness and SMEs (CSES et al, 2015),

[99] Study monitoring the impact of REACH on competitiveness, innovation and SMEs (CSES et al, 2015) such an increase was reported by about a quarter of respondents to the business survey .

[100] Industry stakeholders consulted in the framework of the study for a non-toxic environment strategy (Milieu et al)

[101] PACT and CORAP list –;

[102] REACH - Evaluation of the impact on the affected industries and the whole economy in Austria, Denkstatt, March 2015

effects only to REACH as substitution is also encouraged by other legislation (e.g. OSH) and supported by drivers, such as consumer demands, market circumstances and initiatives such as e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme.

Improving substitution and innovation was one of the topics debated under the Dutch presidency, and the debate[103] concluded that there are clear signals that REACH already promotes substitution of toxic substances in those cases where phasing out is anticipated. It was also emphasised how substitution contributes to innovation and a green economy.

However, there is little clear evidence thus far that chemical legislation in general terms, is in itself a stimulus to more fundamental development of alternative technologies and substances, new business models and non-chemical solutions, as innovation is predominantly market driven (beyond the above mentioned anticipation of phasing out).

Overall it was felt that encouraging innovation was something that would need the active involvement of other policy fields, such as research and economic policy.

Product and Process Oriented Research and Development (PPORD) notifications[104] and registration of new substances

There was an increasing trend for the overall number of Product and Process Oriented Research and Development notifications (PPORDs) [105] although used only by a relatively small number of companies in Europe (~350), which were typically large and mainly from a relatively limited number of Member States. The SME panel[106] revealed that PPORD is perceived as useful or very useful by nearly half of participating companies while nearly a third was not aware of this mechanism. So far, about 20% of the PPORD notifications have led to the registration of the substances concerned, demonstrating that the PPORD notification has the potential to pave the way for new products on the market.

New substances placed on the market are continuously being registered with a steady upward trend[107]. Since REACH has been in force almost 1,500 new substances have been registered.

As a summary, it can be concluded that innovation is certainly taking place, but there is room for more, specifically with respect to the innovation activity among SMEs. REACH mechanisms to foster new products are being used and pave the way for the upward trend to create new substances but they could be extended to more companies from more Member States. SVHCs are being phased out and replaced by safer alternatives, often as a result of innovative thinking and developments.

6.1.1.4. Stakeholder views

Stakeholder views concerning the achievement of REACH objectives differ by objective. Most stakeholders have fairly positive views regarding the improvement of protection of consumers, workers and the environment as well as promoting alternative methods for

[103] Information note from the Presidency to the Council on the policy conference "REACH forward"

[104] Article 3(22)

[105] Report on operation of REACH and CLP, ECHA, 2016

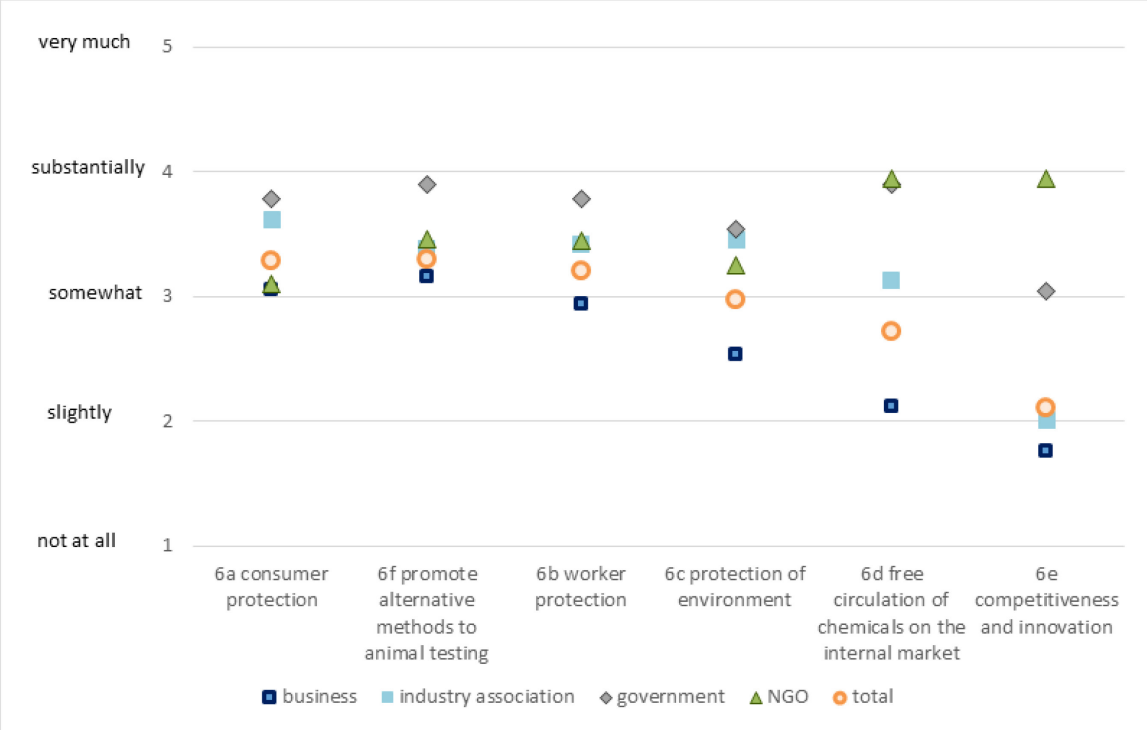
[106] Stakeholder consultation: report of the SME panel

[107] ECHA report 2016

animal testing. Respondents have more diverging views concerning the objectives of free circulation of chemicals on the internal market and in particular competitiveness and innovation. Businesses are rather critical concerning the achievement of the internal market and the improvement of competitiveness and innovation, whereas governments, trade unions, consumer associations and NGOs were much more positive. For example, European environmental Bureau (EEB) considers that REACH is promoting not only EU but global innovation, as the candidate list has become a worldwide reference for substitution.

Figure 3: Question 6 of the online public consultation in relation to the REACH evaluation:

To what extent do you think REACH is achieving the following objectives? (Marker points show average values of responses by stakeholder group and across all respondents)



As regards delivery of results by REACH, all different stakeholder groups express a rather positive tendency on generation of data and information for risk assessment and management. Concerning the shifting of the burden of proof, most stakeholders express positive views, except for NGOs and consumer associations which are more critical in this respect. Consumer organisations flag concerns about data requirements for the approximately 20.000 low volume chemicals, which they consider currently insufficient to achieve a more complete picture of the properties of the chemicals on the European market.

Stakeholders also raise certain issues that hinder the achievement of REACH objectives, mainly the high level of non-compliance of registration dossiers, which also impairs the level-playing field between duty holders. There are also concerns on the enforcement of the 'no data, no market' principle, as non-compliant dossiers are not sanctioned. Moreover, the registration process, as it currently is, induces bad practices such as free-riding in the preparation of joint submission and even more in the updating of registration

dossiers. It was considered that registrants do not have a strong incentive to provide high quality data as they risk to be targeted more often by regulatory actions if they do.

6.1.2. WHAT ARE OTHER EFFECTS OF REACH?

Assessment question: "What have been the effects of REACH (whether socio-economic, environmental or health-related, both positive and negative), including also effects not originally planned?"

Besides the results described in the previous section, REACH is bringing about other effects such as the increased expertise on chemicals for public authorities and industry to carry out risk assessment and risk management. In addition, REACH is seen as the most complete chemical regulation in the world and is thus influencing legislation in other jurisdictions. REACH is also contributing to international harmonisation in the implementation of chemicals policy.

A number of other effects – foreseen or not - have been reported by industry stakeholders in relation to market concentration, withdrawal of substances, the competitive advantage of non-EU producers of articles, increased business uncertainty and possible relocation of activities. There is relatively little evidence for some of these, but where available and relevant they are addressed in detail in other sections.

What is the issue?

The first effectiveness question asked whether REACH is meeting its objectives, including the environment and health benefits (described further in Annex 5 paragraph 1.5). But beyond those intended effects, the implementation of REACH has led to some other effects – either expected or unplanned effects, which are described below. Consultation with stakeholders is the main information source for these other effects.

6.1.2.1. Employment effects

Sale figures for the EU chemical industry remained broadly stable between 2007 and 2015[108], with figures of EUR 524 billion and EUR 519 billion respectively. On the other hand, there has been a gradual reduction in employment in the chemical industry from 2003 to 2013 (from 1.37 million to 1.16 million employees),[109], with a bigger reduction during the period 2003-2008 than the period 2009-2013. Nonetheless, none of the studies reviewed identify any evidence of a correlation between the REACH Regulation and EU economic growth and employment in the chemical industry or downstream users.

There is some evidence that the entry into force of the REACH Regulation has increased the market of REACH-related consultancy (technical and legal) services as a result of activities outsourced by industry and public authorities[110] but no figures are available to quantify those effects.

6.1.2.2. Increased expertise on chemicals

Member State authorities are generally satisfied with the level of technical expertise and the cooperation at EU and national levels[111] although the competences and resources of

[108] CEFIC data: Facts and Figures of the European chemicals industry, 2016

[109] CEFIC data: Facts and Figures of the European chemicals industry, 2016, page 30

[110] Monitoring the impacts on competitiveness, innovation and SMEs (CSES et al 2015), page 140

[111] Review of Member State reports under Article 117(1)

Member States are not equally distributed. The implementation of REACH involves a sharing of the workload (e.g. SVHC identification, restriction proposals) and exchanging knowledge between the public authorities as well as enhancing the coordination of their approaches.

Different bodies and activities organised to exchange expert opinions and coordinate the views of different national authorities such as the European networks (e.g. CARACAL, HelpNet, Forum) facilitate the coordination of Member State activities, ensuring coherence between risk assessment practices at national level and avoiding duplication (see also section 6.5.1.1 on EU added value).

Overall, the level of expertise on chemicals is increasing as a result of cooperation among different Member State authorities through REACH activities. For example, in specific cases such as the preparation of proposals for restriction, ECHA provided support to Member States inviting national experts to spend time in ECHA and gain expertise in the preparation of a restriction dossier (Annex XV dossier) for restriction. Some experts indicated that their expertise increased e.g. on socio-economic analysis as a result.

Industry respondents acknowledge REACH's contribution to the increased knowledge on chemicals, the communication in the supply chain and the substitution of SVHCs but also refer to other, negative effects on the competitiveness and innovation.

6.1.2.3. International effects

REACH is currently the most complete regulatory system for chemicals in the world as further elaborated below. It encompasses a combined inventory and data collection with a self-assessment obligation in registration, with an evaluation of the registration dossiers and the two most commonly applied risk management approaches of restrictions and authorisation. It largely places the burden of proof on industry.

Most pieces of legislation in other jurisdictions have comparable elements with parts of REACH. When looking at the influence of REACH on other legislation outside the EU it is therefore important to consider the policy influence (e.g. on the objectives set), the actual legislative influence and finally the influence of the REACH tools used to implement the legislation.

A study on the impacts of REACH on international competitiveness of EU industry[112] showed that REACH has influenced the chemicals legislation in third countries to different extents. The study looked at the key aspects, which explains many differences in the legislative frameworks in place in the EU and the third countries, such as the principle of where the 'burden of proof' is placed as well as the links to the relevant differences in the legal systems of the concerned countries.

- South-Korea has developed a legislation[113] based on the model of REACH, where the burden of proof lies with manufacturers who have to register their substances, includes post-registration obligations on communication of information in the supply chain, and bans or restricts hazardous substances (no substances are listed as subject to authorisation yet). In addition, there is work ongoing to allow companies in South Korea to use EU data to register chemicals.

[112] Study on the impacts of REACH on international competitiveness of EU industry

[113] Korean regulation: Law No. 11789 Act on Registration and Evaluation of Chemical Substances—"K-REACH" Come into force 1 Jan 2015

- REACH has influenced the legislation in China[114], developing a "REACH like" legislation, although differences in the scope and implementation are substantial (e.g. notification of new substances, proactive compliance practices by industry, prioritisation of chemicals). Due to the chemical management programme being still new compared to EU or US, there is in China some reserve in using QSAR and read across data.
- Some commonalities can be observed with Japan, and regarding information requirements, with Canada e. g. volume, use, exposure and hazard information. The Canadian legislation[115] requires information from companies so that authorities can make an assessment on the risk and management of chemicals categorised in 3 specific priority phases (high, medium and low).
- Major differences remain between REACH and the new legislation in the United States[116], which notably places the burden of proof on the authorities and not on manufacturers to assess the risk on some selected prioritised chemicals similar to how it was in the EU under the previous Existing Substance Regulation (EC) No 793/93.

The scope of the study is limited to five countries, which provides a limited picture of the influence of REACH on third-country legislation and does not allow for firm conclusions on the international harmonisation of chemicals regulation.

In the EU, with REACH, most chemicals are being assessed prior/during registration, i.e. since REACH came into operation already 17 000 unique substances were registered and therefore assessed by industry, which have the burden of proof for placing safe chemicals on the market. Other systems, e.g. that of the US Environmental Protection Agency (EPA) does these assessments only for a limited number of selected chemicals and the assessment is done by the regulatory authorities. By comparison, the 2012 Toxic Substances Control Act (TSCA) Work Plan for Chemical Assessments identified 83 chemicals for assessment by EPA as part of its chemical safety program, and the updated TSCA 2014 Work Plan had a total of 90 chemicals included, for which 4 assessments were concluded. In the last ten years, no new restrictions have been adopted in the US.

Some cost estimates for the registration of new substances indicate that REACH costs are in the middle range compared with other regimes. While the costs per substance under REACH are EUR 86 000, they are EUR 6 500 in the US, EUR 50 000 in Korea, EUR 116 000 in Canada, EUR 120 000 in Japan and EUR 125 000 in China[117].

The differences with other jurisdictions in terms of principles, approaches and processes result in a complex regulatory situation for companies as they must comply with both the regulation in the country where they produce and in their export markets. From the

[114] Several pieces of legislation (non exhaustive): New Chemical Substance Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (2010);Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) (updated in 2013);Hazardous Chemicals Decree 591 – The Regulations on Safe Management of Hazardous Chemicals(comes into force on 1 Dec 2011) - Main Law;Toxic Chemicals Restricted To Be Imported/Exported Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994);List of toxic chemicals severely restricted to be imported into or exported from China(revised in 2011);

[115] https://www.canada.ca/en/health-canada/services/chemical-substances.html

[116] https://www.epa.gov/chemicals-under-tsca

[117] Study on the impacts of REACH on international competitiveness of EU industry

authorities' perspective, a better exchange of the approach and acceptance on some principles would help to have more harmonisation in the control and management of chemicals.

However, the ECHA chemical substances database, containing data collected through REACH processes, notably registration, contributes to the influence of REACH worldwide. According to ECHA, the use of ECHA's data by regulatory authorities outside the EU, and notably authorities in Canada and Australia has increased[118]. The government of Canada, for instance, considers ECHA as a key source of information during substance assessment work.

In addition to the influence on third country legislation, REACH is contributing to international harmonisation in the implementation of chemicals policy. Since 2010, ECHA has signed cooperation agreements with regulatory agencies in four countries: Australia, Canada, Japan and the United States of America. Activities are focused on exchanging information, best practice and scientific knowledge.

6.1.2.4. Stakeholder feedback

The online public consultation carried out in the context of this REFIT evaluation provides an overview of other issues raised by the different groups of stakeholders, including also effects not originally planned. These are, where there is evidence, discussed in Annexes 4 and 5 or under the other evaluation questions:

- Compliance costs and risk management measures (e.g. authorisation and restriction) may have resulted in the possible relocation of some activities outside the EU. (Costs are addressed under efficiency, relocation under Annex 4 paragraph 6.6)
- Difficulties in the registration of low volumes substances may be forcing market concentration. Market consolidation was expected under REACH: this also occurred for the Plant Protection Products[119] and Biocides [120]Regulation but was not seen only as a negative effect. (Addressed under efficiency questions, under Annex 4, paragraph 1.2.2 and Annex 5, paragraph 2.4.2)
- Disruption in the supply chains of certain products because of substance withdrawal. It was anticipated that those substances which were not essential would be taken off the market if the profit margins for a substance could not compensate for the costs of generating safety information (or if there was a close alternative). (Addressed under efficiency questions, Annex 4, paragraph 1.3.1 and Annex 5, paragraph 2.4.2)
- Business uncertainty caused by the placing of a substance on the Candidate List. (Addressed under efficiency questions, Annex 4, paragraph 6.2 and Annex 5, paragraph 2.4.2)
- Competitive advantage of non-EU producers, which can export to the EU articles containing SVHC as they do not need to apply for authorisation. (Addressed under Annex 4, paragraph 6.5.3 and Annex 5, paragraph 2.4.2)

[118] ECHA Report on the Operation of REACH and CLP 2016 page 126

[119] Regulation (EC) No 1107/2009

[120] Regulation (EU) 528/2012

- Re-allocation of R&D resources (staff and budget) towards compliance which hinders market-driven innovation as well as more focus on substitution activities, which can be seen as a driver for innovation. (Addressed under effectiveness question 1 and Annex 5, paragraph 2.6.2)
- Bad practices such as free-riding in registration or the maintenance of dossiers. While the extent of such practices is expected to be limited, they may contribute to a negative perception of REACH by other companies (section 1.7 Public consultation, and Annex 4 part 10).
- NGOs have underlined that the assessment of applications for authorisation disfavours suppliers of alternatives as it focuses on the applicant's perspective. On the other hand, certain affected industries claim the misuse of public consultations as marketing tools for alternatives to substances subject to authorisation.

6.1.3. WHICH FACTORS INFLUENCED EFFECTIVENESS?

Assessment question: "What factors (including external ones) influenced the observed effects and to what extent?"

The effective cooperation between the Commission, ECHA and Member States Competent Authorities has been important for improving effectiveness. In addition, enforcement activities are important: these are increasingly prioritised to ensure that the key requirements of REACH are better implemented, but there is room for further improvements in enforcement, in particular for imported goods. More generally, the EU chemical sector operates in an increasingly global market, and has been affected by developments elsewhere including the global recession.

What is the issue?

This section examines some of the factors influencing effectiveness, and that are otherwise not directly addressed in the analysis above.

6.1.3.1. Coordination between ECHA, the Commission and Member States

The coordination of the public authorities involved in the implementation of REACH is one of the key factors contributing to the achievement of REACH objectives. Bodies intended to facilitate coordination such as the Commission expert group made up of the competent authorities for REACH and CLP (CARACAL) or the network of national and ECHA's helpdesks (HelpNet)[121] are working effectively. The ECHA Committees (MSC, RAC, SEAC) and the Forum provide additional fora for exchanging expert opinions and coordinate the views of different national authorities.

ECHA and the Member States have, among other issues, addressed several new and scientifically challenging issues such as new test methods, read-across and other alternative methods. Furthermore, the activities focused on proper identification and assessment of Substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances, characterisation and safety assessment of nanomaterials and the assessment of complex toxicological modes of action such as endocrine disruption. This has increased scientific knowledge and

[121] HelpNet is hosted by ECHA and aims to ensure consistent responses to companies by National Helpdesks

understanding of the issues among EU authorities, industry, other stakeholders, and the scientific community.

Common screening and the implementation of the SVHC Roadmap are other processes where cooperation between Member States, ECHA and the Commission has promoted a coherent management of substances of concern, and has supported less experienced authorities in joining the implementation work. By that the number of substances addressed did increase. Compliance check and substance evaluation are also processes whose effectiveness is supported by very close cooperation between ECHA and Member States.[122]

In addition to the coordination of public authorities, it is notable the involvement of stakeholders (industry, NGOs, trade unions, etc.) in the bodies and networks organised by the Commission and ECHA that provide platform for discussion and capacity building.

6.1.3.2. Role of enforcement

Enforcement actions by Member States influence greatly the correct implementation of REACH requirements. Member State enforcement strategies are broadly in line with the strategy of the Forum[123] and are an important prioritisation tool to focus activities on actual non-compliance risks.

The organisation of enforcement activities is complex as in most EU and EEA Countries several national authorities are responsible for enforcing different parts of REACH (e.g. health and/or consumer protection authorities, national chemical agencies, labour inspectorates, environmental authorities or customs authorities). Such complexity requires enhanced coordination at national level (e.g. via regular meetings, memoranda of understanding or development of legislation to define responsibilities among authorities).

Effort has gone into improving enforcement and progress can be seen in a number of areas, although it is clear that it can still improve as shown by the indicators on enforcement activity which indicated lower level of compliance in particular with respect to control of imports and supply chain obligations (see Section 5.9 and Annex 4, paragraph 9.1.1 and 9.1.2). For example, market surveillance activities follow the adoption of new restrictions, identifying non-compliant products on the market and taking action by withdrawing such products from the market and notifying other Member States through the RAPEX Network.

The Forum coordination activities have increased from 2011 to 2015, focusing more on the practical harmonisation of enforcement operations through concrete projects[124]. Most Member States (on average 28 of the 31 EU/EEA countries in every REACH Enforce REF project) participate in Forum projects and express appreciation, considering it to be an effective instrument to coordinate and harmonise the enforcement of REACH across the EU, exchange experience, and develop procedures for cooperation between national authorities and ECHA.

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122 See further details in the evaluation section

123 https://echa.europa.eu/about-us/who-we-are/enforcement-forum

124 Further details in the Annex 4, chapter 9.

The results of the Forum's coordinated enforcement projects[125] have shown that the effectiveness of the enforcement activities of the Member States can still be improved in particular regarding registration obligations and Safety Data Sheets where a relatively high level of non-compliance have been found. These are the main tools for identifying hazards and risks and for communication along supply chains, respectively, as well as for controlling imported goods. Custom controls are based on non-compliance risk but nonetheless, insufficient control on imported goods is considered to pose risks for consumer safety as well as prevent an effective level playing field for EU manufacturers. An ECHA Forum project dealing with registration revealed that the highest proportion of non-compliant companies is among only-representatives (34 %), compared to importers (15 %) and manufacturers (6 %). The preliminary results of a Forum project in the area of restrictions show a similar trend, as 10% of EU-manufactured products are non-compliant, while 17% of non-EU products are not compliant and 39% of products of unknown origin are non-compliant.

The enforcement projects also revealed some differences among Member States (i.e. some tend to systematically report higher compliance than the EU average whereas others keep to the lower end). However, no comparable information is available to assess the effect on the internal market.

While the coordination activities of the Forum are highly appreciated, according to the public consultation many stakeholders are of the view that the effectiveness of enforcement is not yet equal throughout the Union and more efforts should be done at national level suggesting targets for enforcement. Up to date, the Commission has started one infringement procedure for a breach of the harmonised implementation of REACH in relation to information requirements for SVHCs in articles[126].

6.1.3.3. External factors

The effects observed and the achievement of REACH objectives are also influenced by factors that are external to REACH. For example, the performance of the EU chemical industry was severely affected by the 2008/2009 global recession and after a rapid cyclical recovery, production has been growing more slowly than global demand since early 2011[127].

Global demand for chemicals is strongly driven by China, India and other emerging countries whose economies (and also chemical sectors) are growing faster than those of Europe and North America, where the EU chemical sector sells most of its products. In addition, energy prices, currency appreciation, the cumulative regulatory and tax burdens[128] or labour costs are important factors that impact on the competitiveness of the EU chemical industry (see also 7.3.3.1 International coherence).

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[125] On the basis of the projects REF-1, REF-2 and REF-3, available at https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

[126] See section 5.4 as regards the infringement procedure in relation to information requirements for SVHCs in articles.

[127] The EU production of chemicals fell significantly in 2008 and 2009 (by -3.4% and -11.8% respectively in volume terms). Production enjoyed a strong recovery in 2010 posting a 10.2 % growth rate compared to the year before (Cefic, Chemdata International).

[128] The cumulative cost assessment for the EU chemical industry (Technopolis 2016) estimated the cumulated weight of all legislation relevant to chemical companies for the period 2004-2014 to represent around 2% of their turnover, 12% of the value added and 30% of the gross operating surplus. The full report is available at: http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

Another factor are the activities of international fora (in particular the OECD) as regards the development, validation and acceptance of alternative test methods determine to a large extent the effectiveness in promoting the use of such alternative methods.

As regards the objective of REACH to increase the level of protection of human health and the environment, other chemicals related legislation (e.g. CLP Regulation) and additional factors also influence the effects observed. For example, the trends observed in the reduction of cases of occupational skin diseases and occupational asthma are not only the result of REACH related factors[129] but also of increased awareness and implementation of the legislation on health and safety in workplaces (see Annex 5, paragraph 1.5), a better knowledge of the hazard properties of the substances, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes (for details see 7.1.1.1 Reduction of risks)[130].

6.1.3.4. Conclusions

REACH's implementation has included efforts to improve the coordination of the main public actors involved, especially through the establishment of mechanisms that avoid fragmentation and increase the efficiency of their work. The effective cooperation between ECHA and Member States authorities in improving the compliance of registration dossiers and between Member States, ECHA and the Commission in the common screening and the SVHC Roadmap implementation contribute to achieving the objectives of REACH.

In addition, enforcement activities are increasingly prioritised through enforcement strategies to ensure that the key requirements of REACH such as registration obligations and communication through the supply chain are better implemented. Whilst improving, there is room for further improvement of national enforcement activities as regards harmonisation throughout the Union, including controls on imported goods. It is also clear that enforcement is still weak in some aspects in particular with respect to control of imports and supply chain obligations and in some Member States.

More generally, the EU chemical sector operates in an increasingly global market and, as evidenced by economic indicators such as sales and employment, the chemicals industry has been has been affected by developments elsewhere including the global recession.

6.1.4. TO WHAT EXTENT IS REACH CONTRIBUTING TO MEETING THE WORLD SUMMIT SUSTAINABILITY DEVELOPMENT (WSSD) 2020 GOALS?

Assessment question: "To what extent is REACH contributing to meeting the World Summit Sustainability Development 2020 goals?"
There has been considerable progress since the first target was adopted in 2002. Notably, many of the targets set out by the International Conference on Chemicals Management (ICCM) in 2006 have been met or are on track to be met by 2020. However,

[129] For example: (better) risk management measures introduced as a result of the registration process, increased communication along the supply chain and further actions via authorisation and restrictions (leading to the withdrawal of some skin and/or respiratory sensitisers)

[130] Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment – Development of a system of indicators, RPA, April 2016

a number of actions needed to fully meet the WSSD 2020 goals have not been achieved yet, such as: information gaps identified in the registration dossiers; better targeting consumers or civil society at large; enhanced delivery of risk management measures

What is the issue?

At the 2002 Johannesburg World Summit on Sustainable Development (WSSD) the target of ensuring "*that by 2020 chemicals are produced and used in ways that minimise significant adverse impacts on the environment and human health"* was adopted. The goal was further developed emphasising the closing link between the chemicals and waste policies, and in 2012 at the Rio+20 summit[131] the revised target was "*to achieve by 2020 sound management of chemicals throughout their life cycle and of hazardous waste in ways that lead to minimization of significant adverse effects on human health and the environment"*. Finally in 2017 this was further refined as the Sustainable Development Goal 12.4

- *"By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment*."

The main differences, for the purpose of this evaluation, of the two goals is the strengthening in 2017 of the 2002 goal by removing 'significant' as a qualifier of the adverse impacts and the introduction of the means of achieving the goal through significant reduction in exposure. This question considers the contribution of REACH to the achievement of both the 2002 and the 2017 targets, which is analysed by using in addition the following:

- the objectives adopted by the International Conference on Chemicals Management (ICCM) in 2006 as part of an Overarching Policy Strategy designed to meet the WSSD target
- the roadmap for actions developed in a 2013 study[132] to achieve the WSSD target.

6.1.4.1. International Conference on Chemicals Management (ICCMs) overarching policy strategy

The ICCM in 2006 adopted an overarching policy strategy in order to operationalise the WSSD goal and to define in detail what is needed to achieve the goal. Therefore, five priority areas were identified in which a number of concrete objectives were specified that countries would have to achieve in order to meet the goal: knowledge and information, risk reduction, governance, capacity-building and technical cooperation, and illegal international traffic. The contribution of REACH to achieving the objectives in the different areas is analysed in this section.

- Knowledge and information – Significant progress is being made under REACH in obtaining more information on chemicals and their potential risks. However, the level of non-compliance to the information requirements in REACH identified shows that less new reliable information has been generated than expected. With REACH, the EU created ECHA and put strong obligations on the Member States and the Commission to

[131] http://www.un.org/disabilities/documents/rio20_outcome_document_complete.pdf

[132] Link to the report on the Interpretation of the WSSD 2020 chemicals

establish a chemical management infrastructure. Equally in industry, the submission of 95% of all registrations as joint registrations shows that the infrastructure built by industry to share information and develop joint dossiers has worked. An expected consequence of this infrastructure is therefore an improved understanding and knowledge of chemical safety issues.

- Risk reduction - The improved knowledge and information as well as improved risk management measures has led to risk reduction. For example, many applicants for authorisation reported improved risk management at the workplace as a result of the preparation of an application for authorisation or as a result of the discussions in ECHA concerning the application (See Annex 4 paragraph 6.5.1. and 6.5.2). Similarly, but to a lesser extent, industry reported improvements as a result of the registration requirements. REACH promotes substitution of SVHCs, though both the restriction and authorisation procedures could still be more effective and efficient. Also, non-compliance to the information requirements in REACH results in SVHCs remaining unidentified and hence in slowing down the phase-out process. Whilst the processes are underpinned by the precautionary principle, the principle itself has not been explicitly applied.

- **Governance** - REACH provides a comprehensive legal framework on chemicals management, completes the infrastructure of the Union by creating ECHA and assigns clear roles and responsibilities to the stakeholders involved. Procedures and tools have been put in place to inform and consult stakeholders and to address their concerns in the implementation of the different REACH processes. Enforcement has been strengthened, but still has weaknesses, and REACH has had a positive influence on international chemical governance.

- **Capacity-building and technical cooperation** – There are some indications that REACH is inspiring chemical legislation internationally and is contributing to improving the management of chemical risks. ECHA has developed a range of comprehensive guidance documents and has carried out awareness raising campaigns to support the implementation of REACH. IT tools for which ECHA contributes, jointly with the OECD, to the continued development such as IUCLID or the QSAR Toolbox, are made available and used globally. These activities contribute to capacity-building at global level and are elements of technical cooperation. (Activities further described under the evaluation question on coherence of REACH with international efforts). ECHA is internationally recognised as source of information for chemical risk management and cooperates with authorities in third countries.

- **Illegal international traffic** - REACH has limited impact on the reduction of illegal international traffic in chemicals, since it does not address export of chemicals. However, REACH provides rules on the import of chemicals, including enforcement and requirements applying to imported chemicals. Therefore, it can be assumed that REACH contributes to the reduction of illegal international trade by protecting the Union from illegal imports. REACH may further help reducing illegal international trade through the improved market control in the Union and the better exchange of information on the legal status of chemicals.

6.1.4.2. Roadmap of actions

The 2013 study[2] (Figure 43, page 346) set out a roadmap of legally mandated, policy and other actions deemed necessary to reach the WSSD 2020 goal. The study explains why these actions are considered necessary to meet the WSSD 2002 goal assuming that the work on evaluation will effectively ensure compliant registrations dossiers and an

efficient implementation of restrictions and authorisation. The following table gives a short overview of which actions were carried out and which ones not.

Table 2: roadmap to reach the WSSD 2020 goal

Roadmap Action	Action
2013	
Registration deadline for phase-in substances >100 t/y by 1 June (Art. 23(2))	Done
Clarify the relationship between OELs and DNELs in ECHA guidance and SDS	Ongoing
Review regarding Endocrine Disruptors(Art. 138(7))	Done
Draft implementing act on nanomaterials by December 2013	Ongoing
Reduce registration fees and other actions for SMEs	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
Improve awareness of REACH and safety data sheets with downstream users	Ongoing
2014	
Review of chemical safety assessment for CMRs 1 June 2014 (Art. 138(1))	Ongoing
Support for the identification of substances and efficient data sharing	Done
ECHA report on non-animal test methods, by 1 June (Art. 117(3))	Done
Tests for physical hazards to be carried out from 1 Jan 2014 (CLP Art. 8(5))	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
2015	
Possibility of implementing act on substance identification and "sameness"	Done
Member States' reports on the operation of REACH, 1 June 2015 (Art. 117(1))	Done
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
2016	
Consider options for the development of rules and guidelines to protect children	Not yet started
ECHA report on the operation of REACH, 1 June 2016	Done

(Art. 117(2))	
Annual update of the Community Rolling Action Plan (Art. 44(2))	Done
Awareness raising on recognition of CLP hazard labels	Not yet started
Industry voluntarily action develop product packaging that is consistent with CLP	Not yet started

The still ongoing or not yet commenced actions are delaying either the efficient generation of information (for example nanomaterials) or information use (all other actions) and hence delaying the ability to ensure that adverse effects are minimised.

6.1.4.3. Conclusions

REACH contributes to meeting the WSSD 2020 goal to achieve the environmentally sound management of chemicals also beyond the EU borders. Indeed, there has been considerable progress since the first goal was adopted in 2002. Notably, many of the targets set out by the ICCM in 2006 have been met or are on track to be met by 2020. However, a number of actions needed to meet the WSSD 2020 goals have not or only partially been carried out such as: information gaps identified in the registration dossiers; better targeting consumers or civil society at large; enhanced delivery of risk management measures. This contributes to the conclusion that it is not likely that the EU will meet the 2020 goal as set out in 2002 and hence also not the one of 2017.

It can therefore be concluded that progress has been made towards meeting the 2020 goal but additional efforts are needed.

6.2. Efficiency

6.2.1. HOW DO COSTS AND BENEFITS OF REACH COMPARE?

Assessment question: What are the benefits and the costs and the corresponding key drivers associated with the implementation of REACH? To what extent are the costs proportionate to the benefits achieved?

Overall, the estimates of benefits and costs available indicate that the costs seem to be justified by the benefits. The biggest source of costs is the registration process: the costs for the first two registration deadlines, which were higher than originally predicted (in part because of mandatory data sharing, which was not considered in the Commission proposal), amounted to a total of EUR 2.3- 2.6 billion (compared to an estimate of EUR 1.7 billion). Even if in the same order of magnitude (the observed costs are approximately 35% higher than forecast), there is still scope to improve the efficiency.

6.2.1.1. Benefits associated to the REACH Regulation

The enabling factors for the benefits are the actions that allow REACH to deliver its objectives of protection of human health and the environment, enhancement of the single market, competitiveness and innovation. These can be associated to each of the processes:

- The REACH Registration requirement leads to new and better physicochemical and (eco)toxicological information for substances (including for their classification), while avoiding unnecessary animal testing and improving the knowledge on their uses and level of exposure, which in turn allows companies to decide on the most appropriate risk management measures to be put in place on site and to communicate these across the supply chain
- The number of substances and registration dossiers going through the Evaluation process, which leads to better information and confirmation (or not) of initial concerns
- The progressive restriction of substances and groups of substances of concern, which contributes to reduce the exposure to chemicals, thus increasing the level of protection of human health and the environment
- The continuous inclusion of SVHC in the Candidate List and in Annex XIV, which leads to these being progressively replaced by suitable alternatives and eventually phased-out; the authorised use assures that the risks from the substances of very high concern are identified, assessed and properly controlled, resulting in an improvement of the workplace conditions and thus increasing the protection of human health and the environment
- The increase in the number of substances with self (CLP) and harmonised classification and labelling (CLH) denotes an improvement in knowledge of the hazardous properties of chemicals. The ECHA database on CLP for substances allows industry to identify differences in how one substance is classified, and this database would, ideally, over time lead to coherent self-classification of substances by companies.
- The exchange of the enforcement activities across Member States.

Human health and environmental benefits

Information allowing the quantification of the health benefits arising from a reduction in chemicals' exposure is partial (at this stage of the implementation, information on trends is limited and is circumscribed to specific substances, uses and/or endpoints). Besides, as originally expected, the full benefits associated to the implementation of REACH will still take time to materialise. Nevertheless, on the basis of the evidence in terms of outputs (e.g. progress on registration) and outcomes (e.g information generated and risk reduction trends) so far, the potential scale of the benefits of REACH remains still as already stated in the 2013 REACH review. For human health over a 30-year period was estimated EUR 50 billion and the avoided environment damage over a 25-year period EUR 50 billion (both figures net present values after discounting).

Most of the interviewees in a survey for a study comparing the impacts of REACH with the corresponding regulations of third countries on chemicals and downstream sectors[133] shared the view that chemicals legislation (particularly REACH) will indeed have positive benefits on health and the environment over the long term. Nonetheless, they were not able to provide any examples of improved working environment, health, or

[133] Impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry, ECSIP, 2016

environmental benefits yet, which is in line with the expectation that most of the benefits of REACH will only be quantified in the coming years.

Some specific evidence confirms the progress towards expected results at this stage and that benefits have started to materialise:

- The 10 years update of the so called REACH Baseline Study[134], which includes a set of indicators to monitor trends in the availability of data for risk assessment and reduction of risks, observes a continuation of the trend that was already noted in the 5 years update showing a reduction of the risks caused by chemicals and an improvement of the quality of substance-specific data available for risk assessment.
- The information generated in the registration process has contributed to building knowledge about chemical substances. It has provided as well transparency about what knowledge is still missing and better awareness of the needs of the upstream and downstream value chains. As a result, 23% of respondents to the survey by CSES et al (2015) launched new products or services thanks to the knowledge gained through the compliance process. Another study (RPA, 2015) concludes that the current registration requirements for low tonnage substances provide about EUR 10 benefits for every EUR 1 of cost and that by increasing the information requirements, there would be a roughly proportional increase in benefit in terms of damage costs avoided[135] (although the affordability by industry of potential increased information requirements remains uncertain).
- The benefits of the information generated under the Evaluation processes (dossier and substance evaluation) should complement the benefits generated by the registration, with their efficiency offset by the additional procedural cost that is however still below the cost for the data generation. As a more intangible but crucial benefit, as concluded in the specific section, they are, in conjunction with the regulatory management option analysis (RMOA) by Member States, an essential part of the system that ensure its consistency and improve the communication with industry, thus providing for an equal playing field for companies and contributing to the achievement of the overall benefits of REACH. The conclusions from the Impact Assessment for the modification of the REACH Annexes to ensure that the Regulation is fit for the purpose of nanomaterials[136] can also be applied to the Evaluation process that a better knowledge, where necessary through additional testing, means a better basis for the implementation of more appropriate risk management and, thus, increased avoided human health and environmental damage, as well as new innovation potential, improved trust for investors that there are no hidden liabilities and general demand side trust in the safety of products.
- The health and environmental benefits of the restrictions adopted during the reporting period for this review have outweighed the costs of their

[134] REACH Baseline Study – 10 years update, Öko Institut et al, commissioned by the European Commission, November 2016

[135] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015

[136] Impact assessment to be published

implementation. It is estimated that 9 of the restrictions submitted and adopted in this period under Article 68(1) for the introduction of new restrictions, as well as the amendment of current ones, produce health and environmental benefits of more than EUR 380 million per year, and a reduction of about 70 tonnes of releases of substances of concern, resulting in positive health impacts or removed risk for thousands of consumers and workers (compared to an estimated cost of about EUR 170 million per year)[137].

- Further benefits, although not quantified, can be expected from the specific restriction of CMR 1A and 1B substances in mixtures or in articles supplied to the general public[138].
- The benefits estimated in the two impact assessments[139] accompanying the first and second amendments to the Directive on carcinogens or mutagens at work[140] associated to the setting of exposure limit values for Chromium (VI) and Trichloroethylene are of, respectively, EUR 591 million to 1.7 billion and EUR 118 to 430 million for the period 2010-2069 related to avoided cancer cases. As explained in the Annex 5 paragraph 1.5, these values can be used to estimate the minimum benefits expected for the same substances listed in the Authorisation list (Annex XIV) which, on their own, cover 73% out of the 60 first applications received by ECHA.
- In the case of individual authorisations granted, the benefits calculated in the socio-economic assessments established by applicants for authorisation for 30 uses of 17 substances showed that the benefits of continued use of the authorised substances would amount to EUR 32-38 million per applicant per use[141]. ECHA further stressed in a later assessment that the socio-economic benefits of the authorisations granted for the first 60 uses would amount to EUR 4.6 – 6.4 billion per year[142.143]
- Companies have improved their risk management procedures; as a matter of fact, according to CSES et al (2015), because of REACH 53% of companies say to

[137] Study 'Cost and benefit assessment in the REACH restriction dossiers' published on April 2016. Please note that these figures include only the quantified and monetised benefits, and thus do not represent the absolute value of the benefits of the adopted restrictions. The benefits figures presented in the ECHA report (benefits of over EUR 700 million, reduction of 190 tonnes of substances of concerns) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[138] From 2010, the Commission has restricted more than 600 substances in mixtures sold to the general public.

[139] SWD(2016) 152 final; SWD (2017) 7 final

[140] Directive 2004/37/EC

[141] Report on the operation of REACH and CLP, European Chemicals Agency ECHA, May 2016

[142] Benefits and Costs of Authorising the Use of Substances of Very High Concern under REACH, presentation given at the 9th annual meeting of the Society for Benefit-Cost Analysis (Washington D.C.), Vainio M., Peltola J., Rheinberger C.M., 16-17 March 2017

[143] In the context of the individual authorisation decisions, benefits are the avoided costs for industry (opportunity cost that society would have to bear if the applicant could no longer use the substance applied for) and costs are the monetised costs that arise from damage to humans or the environment

have improved their risk management approach at the workplace and 39% to have improved their management and control of environmental emissions and waste.

- CSES et al (2015) collected some views that the candidate list and other communication instruments (Public Activities Coordination Tool - PACT and CORAP list) are increasing transparency and provide guidance for companies on research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.
- More and more evidence starts accumulating that substitution is already happening as a result of a substance being listed on the Candidate List and the recommendation on priority substances for inclusion into Annex XIV, and when an intention for restriction is published in the Registry of Intentions (ROI) or through the investigation of analysis of alternatives in the Annex XV dossier for restriction. Indeed, from the sample of respondents affected by the inclusion of a substance in the candidate list, CSES et al (2015) concluded that about 9% had launched initiatives to develop new substances and 30% had launched initiatives to find an alternative formulation. The response of companies to the inclusion of substances in Annex XIV (Authorisation list) was broadly similar. According to Milieu et al (2017)[144], the legislative requirements are seen as the main driver of substitution, with respondents to their survey indicating that placing a substance on the Candidate List for Authorisation is the key mechanism that initiates the search for safer alternatives. ChemSec provides in the report *"The bigger picture"* a number of illustrative examples of companies that have decided to anticipate regulatory pressure and to undertake substitution[145], although not in direct relation to REACH.
- Product and Process Oriented Research and Development (PPORD) is perceived as a useful tool by Industry, as concluded by the SME panel[146]. Indeed, data from ECHA show that there is an increasing trend for the overall number of PPORD notifications. So far, around 20% of them have led to the registration of the substances concerned, demonstrating that the PPORD exemption has the potential to pave the way for new products on the market.
- The recent communication from the Commission on the 'Modernisation of the EU Occupational Safety and Health Legislation and Policy'[147] states that the "Protection of workers from exposures to dangerous chemicals is fostered by the occupational and safety health chemicals directives and significantly reinforced by the REACH Regulation and other legal acts regulating chemicals".

Innovation and internal market benefits

These benefits have been examined in the effectiveness questions. Briefly, to recap:

- There have been positive impacts of REACH in terms of delivering an internal market. The wider cost impacts are considered in the following section.

[144] Link to the study for the strategy for a non-toxic environment of the 7th Environment Action Programme

[145] The bigger picture, assessing economic aspects of chemicals substitution, ChemSec, 2016

[146] Stakeholder consultation: report of the SME panel

[147] COM(2017) 12 final: Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy

- Overall impacts on innovation are complex. As observed in the REACH Review 2013, on the one hand, for some companies REACH leads to an increase in resources spent on R&D and to the use of the information generated for compliance with REACH for the conception of new products. On the other hand, the need to ensure compliance leads to diverting R&D resources that would otherwise be available for other innovative activities. However, the increased availability of information of substances and increased communication across the supply chain enable the users of chemicals to make better choices in the design of products and in their use.
- Furthermore, the listing of SVHC in the candidate list or in Annex XIV triggers communication across the supply chain, initiates substitution activities at all supply chain levels, and triggers considerations of reformulation for some products and of withdrawal for some others. The continuous inclusion of new substances in the candidate list and in Annex XIV is however associated with uncertainty and perceived as a challenge for international competitiveness. On the other hand, data confirm that there has been a continuous flow of new substances on the EU market.

Table 3: Benefit summary

	Type of benefits	Monetised benefits (where available)	Remarks
Registration (including communication in the supply chain, i.e. extended Safety Data Sheets)	Information generated		Latency period
	Improvement of data available for hazard assessment (Classification &Labelling)		
	Improvement of data available for risk assessment		
	Improvement of risk management procedures, resulting in a decline of risk scores		
Dossier and substance evaluation	Complementary to registration process: generate additional knowledge about chemical substances		Latency period
Authorisation			
	Potentially avoided cancer cases from use of Chromium VI compounds and trichloroethylene	EUR 591 million – 1.7 billion (2010 - 2069) EUR 118 million – 430 million (2010-	Estimates associated to the setting of exposure limit values for those substances

		2069)[148]	under OSH legislation. Figures provided for illustrative purposes
Restriction	Health benefits derived from reduced risks for workers and consumers	EUR 380 million per year	Expected benefits of new restrictions adopted under the REACH "standard" procedure[149]
	Environmental benefits derived from reduction of 70 tonnes of releases of substances of concern		

Conclusion on the benefits

Suitable datasets to quantify health and environmental benefits arising from a reduction in chemicals' exposure are largely missing and those that exist are representative for some national situations only. A direct comparison with the estimates provided in the Extended Impact Assessment is thus very difficult, but nevertheless the scale of potential benefit of REACH remains still, as already stated in the 2013 REACH Review, at least EUR 50 billion for human health by 2030 and EUR 50 billion for the environment by 2025.

When looking at the specific actions under REACH, it can be observed that some of those benefits are already materialising.

6.2.1.2. Costs associated with the REACH Regulation

Direct compliance costs

Whilst the different actions of REACH facilitate the benefits, they also have direct costs. These are analysed in Annex 5 in more detail.

Registration

Among the REACH processes, Registration remains the main cost driver for EU industry, as it has the largest impact on business activity (production, prices, downstream sectors).

The cost drivers in the registration process are associated to the fees, which can vary according to the volume of the substance (the higher the volume, the higher the fee) and the size of the company (as SMEs benefit from lower registration fees), and to the preparation of the registration dossiers, which can vary according to the complexity of the dossier (depending on the intrinsic properties of the substance, the volume placed on the market and the use spectrum of the substance), the level of data sharing between registrants, the complexity of the Substance Information Exchange Forum (SIEF) and the

[148] Caveat: trichloroethylene is mainly used as intermediate

[149] Article 68(1)

availability of information (e.g. already existing information vs. new tests to be performed).

According to the General Report on REACH 2013[150], ECHA's fees in some cases represented 50% or more of the total costs companies incur when registering, especially in the case of simpler registration dossiers and smaller firms. In the case of more complicated dossiers, data collection, costs related to SIEF and consortia (including management and other fees) were the main cost elements. According to ECHA, "the major cost item in Registration is formed from the costs of compiling and generating the necessary data to fulfil the REACH information requirements", when registration fees only represent a minor part of the overall cost of registration.

The results from the Online Business Survey conducted by CSES et al (2015) confirm the views of ECHA, and suggest that the two costliest activities in the registration of substances in the tonnage band 100 to 1 000 tonnes (2013 registration deadline) were those associated with the fulfilment of the information requirements and with the preparation of the registration dossiers, while the registration fees represented 14% of the costs only.

The *Extended Impact Assessment* of the Commission accompanying the proposal on REACH estimated testing and registration costs of REACH to amount to EUR 2.3 billion in 2003 values (EUR 2.6 billion in 2011 values[151]) over the 11 years planned for completing the registration of all substances. This amount includes registration fees, estimated at EUR 300 million, registration costs, estimated at EUR 500 million, testing costs estimated at EUR 1 250 million (assuming the validation and acceptance of QSARs can be applied within this timeframe), costs linked to safety data sheets, estimated at EUR 250 million, authorisation procedures, estimated at EUR 100 million, and savings of EUR 100 million for new substances below 1 tonne. Compulsory data sharing was not considered in the extended Impact Assessment as it was not envisaged in the original Commission proposal.

For the first registration deadline of 2010, which concerns phase-in substances produced or imported in quantities over 1 000 tonnes[152], the Extended Impact Assessment had anticipated a cost of around EUR 1.15 billion for the industry, when recalculated into 2011 prices. According to the General Report on REACH 2013, the industry survey of 2011 concluded that the cost incurred by duty holders had been higher than forecast, EUR 2.1 billion (with a broader range of EUR 1.1 - 4.1 billion). Although in 2011 there was a significantly lower use of QSAR compared to what was anticipated in the Extended Impact Assessment, this was partially compensated by a higher use of read-across than expected. The difference between the 2003 estimate and the 2011 survey comes thus from the reporting of sums paid by firms for participating in the SIEFs and for accessing data from existing studies (these payments between companies were not included in the 2003 Extended Impact Assessment as they are not a net cost to the sector,

[150] General Report on REACH 2013, European Chemicals Agency (ECHA), April 2014

[151] Cumulative cost assessment CCA for the EU Chemical Industry, Technopolis Group, commissioned by the European Commission, April 2016

[152] Phase-in substances are substances that have been on the European market for a long time, unlike non-phase-in substances, which are all those newly invented; phase-in substances are subject to three different registration deadlines (2010, 2013 and 2018), depending on the tonnage band (between 1 and 100 tonnes, between 100 and 1 000 tonnes, and over 1 000 tonnes, respectively), whereas non-phase-in substances must be registered at any time before their placing in the market

and relate rather to transfer payments that benefit companies that had already undertaken testing – they are not a cost of REACH for the sector as a whole and should thus not be included in the overall cost assessment).

CSES et al (2015) focused on the 2013 registration deadline and estimated that the total costs incurred by companies (including registration, testing and safety data sheets) was of the order of EUR 459 million, for the 2 998 phase-in substances registered in 2013 deadline[153]. These estimations are within the range of the costs anticipated in the *Extended Impact Assessment*.

Under these estimates, the first two registration periods cost approximately EUR 2.1 billion (2010) and EUR 459 million (2013) respectively. Adjusting these figures for transfer payments between firms gives a cost of around EUR 2.3 billion in total[154].

Other relevant findings are that:

- The average cost per substance (covering registration, testing and SDS) from the study surveys is around EUR 153 195 when, for the same cost items, the Extended Impact Assessment anticipated a cost per substance of EUR 193 367[155].
- The study on monitoring the impact of REACH on innovation, competitiveness and SMEs[156] provided estimates of the costs of producing and translating extended SDS as part of the 2013 registration activities. The average costs related to SDS (per registered substance) were estimated at EUR 36 358, which is higher than the estimate in the Impact Assessment accompanying the REACH proposal (EUR 19 844). The comparison by company size suggests that the costs of producing extended Safety Data Sheets appear to be moderately higher for SMEs compared with larger enterprises. A plausible explanation is that the SMEs need to learn and familiarise with those obligations, whereas larger enterprises already gained more experience as part of 2010 registration.
- In order to provide an estimate of the 'typical' costs borne by companies, the study provided median costs per substance and per registrant for substances registered in the 100-1 000 tonnage range. These were EUR 5 763 for producing extended SDS and EUR 4 473 for translation. Furthermore, these figures show that the median costs were somewhat higher for SMEs (EUR 11 899 as the total of producing extended SDS and translation) than for large companies (EUR 8 016).
- There are also costs associated with duty to communicate information on substances in articles (Article 33 of REACH), and with Risk Management Measures undertaken downstream. Additional direct costs may result depending on the duty holder role.

[153] These estimates have been built from the results of the Open-ended online business survey (OBS) conducted for the study, which gathered 566 responses from all types of duty holders. The scope for error within this estimate is potentially large given that it is based in a combination of estimates and relatively small proportion of respondents to the survey as a whole (86/566 or 15%)

[154] ECSIP (2016): the cost model includes an assumption that these transfer payments account for 11 % of the registration costs, but this estimate is subject to uncertainty

[155] Own calculation based on the estimates provided in the *Extended Impact Assessment*

[156] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (CSES, RPA, Okopol 2015) http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations

- CSES estimated the costs of registration for the 2018 deadline. The estimates for the 1 to 10 tonnes substances appear to be in the range of the Extended Impact Assessment (EUR 228 million compared to the estimate of EUR 295 million), but the total cost of registering 10 to 100 tonnes substances is estimated to be significantly higher than formerly estimated (up to EUR 1 136 million as compared to EUR 581 million). This is partially explained by the fact that this last estimation is based on a worst case scenario with the assumption that validation and acceptance of negative and positive QSAR and read-across does not occur within the time frame envisaged in the earlier Extended Impact Assessment.

The studies discussed above have mainly considered the costs incurred by the registrants (manufacturers, importers and only representatives). The specific costs incurred by distributors are briefly described in both the Technopolis Group (2016) and CSES et al (2015) studies, but have not been quantified. These costs have been mostly linked to the pre-registration obligation (pursuant to Article 28 of REACH) and the preparation, translation, coordination, update and modification of Safety Data Sheets.

A check on the findings above, which are based on responses from industry for the large part, are the actual fees and charges paid to ECHA. The fees and charges revenue over the period 2007-2016 was EUR 581 million and the EU balancing subsidy amounted to EUR 225 million. However, the revenue (which is included in the registration cost estimates above) includes payments by non-EU firms (who account for half the registrations) and also payments for other services.

Evaluation

The drivers for the costs are the cost for the registrants to generate the required information, and the 'overhead' for all actors in identifying substances and information needs through the formal process. The generation of information following dossier evaluation is driven by information gaps, either due to lack of high tier information (testing proposals) or non-compliance with the standard information requirements (compliance check). There is also uncertainty for manufacturers, about the ultimate cost of registration of the substances under evaluation, and for downstream users, about the ultimate development cost of the products necessitating those substances. It may also lead to product withdrawal, with the associated knock-on effects for the firm concerned by the withdrawal, upstream suppliers (if present) and downstream users, although there is limited evidence of this so far.

The cost for generating data under dossier evaluation were estimated to be for the period 2009 - 2016, only for the 1 907 requests on 'super-endpoints' in the 1 695 final decisions, in the order of EUR 200 million[157]. It should be noted that these costs should be attributed to registration, as they are merely covering the information gaps due to pending registration obligations or non-compliance.

[157] See chapter 5, subchapter on Evaluation, for more details. Super-endpoints cover most important information from the perspective of integrated regulatory strategy. Other requests beyond these endpoints were made as well. No precise cost figures are available; this estimate is based on the statistics on the number of individual data requests in the period and the costs per each test as used in the draft Impact assessment accompanying the Proposal for revision of REACH Annexes on nanomaterials. As the proposal is still in decision making, the impact assessment has not yet been published

For substance evaluation, the combined cost estimation is not available but is comparatively smaller due to a much lower number of substances addressed; in the same time interval, 82 decisions were issued. In 26 decisions taken in 2016, 84 data generation requests were made. While the requests are of course very case specific, tailored only to the information required to clarify the concern, they can be assumed to be in cases substantial for the individual companies addressed by the decision.

Evaluation is however also time and resource intensive for the Competent Authorities: excluding the time to perform the test itself, the average time for dossier evaluation is 461 days, and for substance evaluation more than 2 years. For the latter, an additional time for placing the substance on the list prior to the assessment (13 months on average) needs to be counted. In order to provide support to Competent Authorities in the work they perform for substance evaluation, ECHA decided to transfer a proportion of the fees collected by ECHA to Member States. The estimated average time in this Decision is of around 65 days for year 2017[158].

According to ECHA's 2016 Final Work Programme[159], 106 Full Time Equivalent (FTE) are dedicated to evaluation (this includes both dossier and substance evaluation assessment and decision making, as well as the evaluation decisions follow-up, management, scientific support and related IT development). Significant effort is put into the evaluation also by MSCA[160] and the Commission[161], but no consistent information is available.

Authorisation

The main cost driver for actors that have substituted Annex XIV substances before their sunset dates, and therefore their uses did not need an authorisation, lies in costs of substitution. The main direct cost drivers for companies applying for authorisations are the fees, the preparation of the application, including charges for consultancy services, and the interactions with authorities after an application is submitted. There are further follow-up costs for companies, including those resulting from the compliance with the conditions set out in the granted authorisations, R&D costs, the adaptation of the production process or the implementation of the alternative.

From industry's perspective, the biggest cost driver is the uncertainty about the future legislative requirements for the substances that companies manufacture or use. Such uncertainty arises already at the stage of placing a substance on the candidate list and is in general associated with potential negative effects on investment decisions and/or on the choice by companies on where to locate their production facilities. Evidence of this actually happening is however limited to anecdotal facts and the issue would need to be studied further.

Direct costs of applications for authorisation for companies include fees paid to ECHA

[158] Decision of the Management Board on the financial arrangements for the transfer of a proportion of the fees to the Member States, December 2014

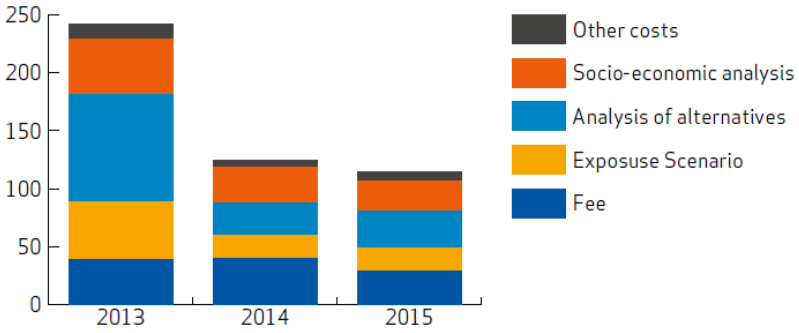
[159] ECHA's Work Programme 2016, European Chemicals Agency ECHA, December 2015

[160] Commenting all evaluation draft decisions and performing as an evaluating authority for the selected substances under substance evaluation. For example, the figures reported by Member States for persons-day dedicated per year to dossier evaluation vary from 0.02 to 1 000 and the figures for substances evaluated (2012-2014) from 0 to 18

[161] The Commission is required to process all evaluation decisions for which no unanimity has been achieved in the ECHA Member States Committee

and the administrative cost of preparing, submitting and defending the application dossier. The costs of the applications have been estimated by ECHA (2016) to be currently around EUR 120 000 per use per applicant in 2016 (in average), down from nearly EUR 230 000 in 2013 (reduction of about 50%)[162].

Figure 4: Application costs per applicant per use in 2013-2015



Source: ECHA, 2016

However, there are administrative burden and capital costs not taken into account in these figures, such as the time to prepare the applications for authorisation or the subsequent costs of complying with certain conditions of the authorisations imposed by the Decisions, and costs of substitution. The data available from ECHA include only the costs of preparing an application for authorisation, but no information on R&D and capital cost of substituting or costs of fulfilling the conditions of authorisation (monitoring, improving risk management etc).

Restriction

The main cost drivers for industry are the substitution of the concerned substances by their alternatives or the compliance with the newly set thresholds or content limit values due to the availability of reliable analytical methods. There can be additional indirect costs linked to the non-availability of the restricted substance or constraints in the use (which would affect the production costs and the price of the final product). The costs for Member States when submitting a proposal for restriction occur mainly when preparing the dossier (data are not always easy to retrieve[163], lack of expertise or resources) or when the proposal does not pass the conformity check and additional information is requested to Member States in order to have the dossier in conformity. Other general costs for all Member States are those related to the enforcement of the restrictions, once they enter into force.

The report on *Cost and benefit assessments in the REACH restriction dossiers*[164]

[162] The estimates are based on a systematic collection of application costs from ECHA, no explanations are provided in ECHA's report about the causes, although it may be assumed that the reduction is linked to a better expertise from applicants as well as a better understanding of the applicants with regard to the information required by the ECHA scientific committees

[163] Report of the Task Force on Restriction Efficiency, European Chemicals Agency ECHA, October 2014

[164] Cost and benefit assessment in the REACH restriction dossiers, European Chemicals Agency ECHA, April 2016

evaluates the total substitution costs linked to restrictions in the EU to EUR 290 million per year. Variation between cases is however significant, between EUR 0 and EUR 100 million per year per case, and the five most expensive restrictions contributed to around 88% of the total costs. Based on that study conducted by ECHA, it is estimated that 9 of the restrictions submitted and adopted during the review period under Article 68(1) for the introduction of new restrictions and the amendment of current ones have an estimated cost of about EUR 170 million per year[165].

Indirect costs

The indirect costs are mainly generated by the withdrawal of a substance from the market due to economic reasons (e.g. the registration cost is too high), or by the withdrawal of a substance from the EU market in certain uses following a restriction or a change in classification. For example CSES et al (2015) show that near to one third of companies (including downstream users) have reported to be affected by a withdrawal of a substance from the EU market due to registration costs. According to affected companies in a case study[166], this leads to R&D expenditure for reformulating mixtures, increased manufacturing costs and increased price of substances, loss of markets or even ceasing business activity and supply chain effects (e.g. the impacts of substance withdrawal and increased price on downstream users).

CSES et al (2015) concluded from their survey results that the 2013 registration deadline is unlikely to have resulted in a significant increase in prices of chemical substances, as the main reaction from companies was to absorb costs rather than increase prices to recuperate costs. The survey results suggest that only around 20% of companies increased their prices, which implies that, overall, the REACH registration in 2013 is unlikely to have resulted in a wide ranging increase in prices across all registered substances.

Other examples of costs transferred to downstream users are the cases where costs of application for authorisation fell on downstream users as a result of chemical suppliers not applying for small volume uses, for which the cost of the application was not profitable. An example is the in-vitro diagnostic industry that typically tends to use smaller amounts of critical substances relative to the end-user clinical laboratories.

Table 4: Cost summary

	Costs quantified[167]	Remarks
Industry costs		
Registration (including also communication in the supply chain, i.e.	Overall estimated costs for 2010 and 2013 registration deadlines	Estimates based on two surveys. Compared with EUR 1.7

[165] This figure includes only the quantified and monetised costs, and thus do not represent the absolute value of the costs of the adopted restrictions. The costs figures presented in the ECHA report (costs of about EUR 290 million) differ from the ones presented above as they also include restrictions outside the reference period, i.e. the 4 restrictions submitted before the reference period and restrictions processed by ECHA but still in the decision-making process of the Commission (NMP, Methanol in windshield washing fluids, D4/D5 in personal care products)

[166] 31 companies participated in the case study on the business impacts of withdrawals

[167] Other costs could not be quantified but are described in the text above

extended Safety Data Sheets)	EUR 2.3 – 2.6 billion Costs/substance (2013 deadline) - Average EUR 153 195 - Extended Safety Data Sheet EUR 36 358 Costs/substance and registrant - Median Extended Safety Data Sheet EUR 10 236	billion estimated for the extended Impact Assessment. The main reason for this difference appears to be the limited use of the QSARs testing method, in contrast to initial expectations.
Dossier and substance evaluation	Dossier evaluation (2009-2016) EUR 200 milion	Estimates for 1907 requests on "super-endpoints"
Authorisation	Substitution costs could not be quantified Application for authorisation costs per use per applicant – EUR 250 000 in 2013 EUR 120 300 in 2015 - 2016	
Restriction	EUR 170 million per year	Expected benefits of new restrictions adopted under the REACH "standard" procedure[168] Mainly substitution costs (higher prices of alternatives and investment costs). In some cases the lost consumer surplus, enforcement costs and compliance control costs to industry were quantified.

Conclusion on the costs

Overall, the main direct costs under REACH are observed to be mainly arising from the registration obligations and from the communication of information along the supply chain (extended Safety Data Sheets). Whilst there is some uncertainty over the costs incurred so far, the costs for the first two registration deadlines appear to be between EUR 2.3 -2.6[169] billion, in the range of the Impact Assessment. The evaluation costs can

[168] Article 68(1)

[169] This range reflects some uncertainty regarding the value of transfer payments

still be significant, in the order of EUR 200 million only for dossier evaluation (for the period 2009-2016). The costs of the restrictions adopted during the review period are estimated to be EUR 170 million per year. The costs for the authorisations have been quantified in relation only to the preparation of individual applications for authorisation, currently around EUR 120 000 per use per applicant in 2015 (in average), down from nearly EUR 250 000 in 2013 (reduction of about 50%).

There are also indirect costs triggered by registrations, authorisations and restrictions.

6.2.1.3. Proportionality of the costs to the benefits

Direct comparison between quantified costs and benefits can be made for the time being only for the Restriction and the individual applications for Authorisation.

Calculations from ECHA (2016) show that the expected health and environmental benefits of the restrictions outweigh the estimated costs of their implementation. The estimated annual cost of the restrictions adopted during the reporting period is more than EUR 170 million per year, while the monetised benefits reach EUR 380 million per year.

As for the authorisation process, the overall benefits for the human health and environment result from reduced exposure and emission of substances placed on the authorisation list through their substitution and the improvement of risk management at the workplace. These overall benefits have not been quantified; however, estimations of avoided costs related to occupational cancer cases provide an approximation of the human health benefits. Costs have been quantified only in relation to the preparation of individual applications for authorisation. The comparison between benefits and costs should thus be taken with caution when assessing the overall efficiency of the authorisation process.

Granting authorisation allows for continued use in justified cases, i.e. when risk is adequately controlled or when socio-economic benefits outweigh the risk. The case-by-case evaluation involves assessment of costs and benefits of continued use for individual authorisations, and so allows for avoiding excessive costs. The application costs of EUR 120 000 per application per use represent 0.2% of the benefits of EUR 32-38 million per applicant per continued use. One published article on the *Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH* also confirmed that the application costs are low compared to the benefits of continued use[170]. However, even if still low compared to the benefits, it could be inferred from the responses from companies in the CSES study (2015) and in the SME panel that the costs may still be significant for SMEs. The socio-economic benefits of the continued use of up to 366 metric tonnes per year of 17 different substances would amount to EUR 4.6 – 6.4 billion per year, to be compared to monetised health impacts in the range of EUR 230-340 million per year.

A study made in the UK on environmental legislation[171] shows that the implementation of chemicals legislation, transposed mostly from European regulation, would provide a best benefit cost ratio of 20 to 1 in the medium-long term. Although this study has limited direct applicability to the benefits attributable to REACH, it is relevant to illustrate the potential benefits/costs ratio of EU chemicals legislation.

[170] Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH, Philipp Hennig, 2016

[171] The costs and benefits of Defra's regulations, Defra, 2015

6.2.1.4. Views of stakeholders

Respondents to the open public consultation showed a mixture of positive and negative views to the question of proportion of costs on registration and information in the supply chain. Concerning the costs linked to dossier and substance evaluation, negative views are slightly more pronounced (around 40%) than those holding positive views (20%), with the rest thinking that costs are somewhat proportionate. For costs related to restriction, positive views are slightly more common. Negative views prevail to a large extent for costs related to authorisation and to requirements for substances in articles, for which large shares (30% - 40%) think that costs are not at all proportionate. However, NGOs, consumer associations and public authorities hold much more positive views than the other stakeholder groups on the proportion of costs related to all of the mentioned chapters.

6.2.1.5. Conclusion

The data gaps reported above make it difficult to draw direct statistically robust comparisons between the costs and any identified or potential benefits that may result from the implementation of REACH. It needs to be stressed that any conclusion at macro level does not prejudge whether compliance costs are sustainable for SMEs.

With the evidence at hand, it can, however, be concluded that:

- The Registration costs have been somewhat higher than anticipated in the Extended Impact Assessment, which can be explained by the administrative costs of mandatory data sharing (not considered in the Impact Assessment as it was not envisaged in the original Commission proposal) and less than predicted use of QSARs. Overall, the registration costs for the two first registration deadlines in 2010 and 2013 appear to be between EUR 2.3 -2.6[172] billion, in the range of the Extended Impact Assessment, which anticipated costs of around between EUR 1.7 billion.
- Although there is limited data on indirect costs, the costs of registering the substances have been absorbed by the chemicals industry, rather than passed on further down the supply chain.
- It needs also to be stressed that while the large bulk of costs have already occurred with the two first registration deadlines in 2010 and 2013, most of the expected associated benefits will only be quantified later.
- It is too early to conclude on the costs and benefits from Evaluation, but it can be asserted that it is an essential part of the system to ensure that the objective of protecting health and the environment is met and to allow a level playing field amongst registrants.
- The data requirements for the Restriction process are clear for the Dossier Submitter although the collection of that data is still difficult for most of the Member States. The benefits of the restrictions adopted during the review period clearly offset the associated costs. In addition, more benefits result for the environment (see Annex 5, part on benefits) and are expected from the restriction of CMR substances in mixtures sold to the general public, as well as from reducing potential exposure to CMR substances through consumer products.

- As for the Authorisation process, the overall benefits and costs of the process as a regulatory risk management instrument have not yet been quantified. However, the case-by-case evaluation of costs and benefits of continued use of a substance allows for avoiding excessive costs from the societal perspective. There are clear indications that the socio-economic benefits of the continued use of the substances for which authorisations have been granted, or conversely, the avoided costs which would have been caused by not using those substances, outweigh the risk for human health and the environment by a significant margin. There is evidence that substitution is happening and that companies are improving their risk management measures, which are direct indicators of the benefits of the Authorisation process.

Overall, the estimates of benefits and costs available indicate that the costs seem to be justified by the benefits. This is not to say that there is not scope to improve their efficiency, or to comment on the proportionality of the burden for an individual firm.

6.2.2. HOW ARE COST DISTRIBUTED BETWEEN DIFFERENT STAKEHOLDERS?

Assessment question: Was the distribution of costs proportionate between the different stakeholders (e.g. larger companies vs SMEs, or among different industrial sectors)? To what extent are there unnecessary burdens on stakeholders?

The evidence available so far provides indication about how REACH has impacted companies of different size or different sectors. Compliance costs affect the business activity of SMEs, which remain more vulnerable than large companies. On the other hand, the support provided to smaller companies to comply with REACH is perceived as useful, although there is still margin for improvement.

6.2.2.1. Impact of compliance costs on SMEs and on larger companies

Two studies (CSES, 2012[173] and CSES et al, 2015), as well as the open public consultation and the SME Panel carried out in the framework of this evaluation[174], indicate that there are some differences between large companies and SMEs in terms of the economic impacts of REACH.

Compared to SMEs, larger companies have in general more resources and markets from which to recover costs, greater financial capacity to make upfront investments as well as a larger capacity to recruit specialised staff to deal with REACH compliance. Small or micro-firms are also often more dependent on one or a few specific chemical substances than large companies. Furthermore, SMEs depend more on the use of external service providers to ensure compliance with REACH[175]. As a consequence, the business activity of SMEs has generally been more affected by REACH.

[173] Interim Evaluation: Functioning of the European chemical market after the introduction of REACH, CSES, 2012

[174] Report on the results of the REACH Evaluation open public consultation, Milieu, 2017 and SME panel, 2016

[175] In the CSES et al survey (2015), large firms reported more often than SMEs that they have a dedicated REACH unit (33% compared to 17%) and more often have a dedicated REACH manager (48% compared to 29%)

Since the REACH Review 2013, several support measures have been introduced to alleviate the burden on SMEs. Among those, the registration fees were revised and reduced for SMEs (an additional 5% compared to the earlier situation and applicable already for the 2013 registration deadline). Furthermore, an Implementing Regulation on data sharing was adopted and entered into force on 25 January 2016 to benefit SMEs from a fairer and more transparent framework. The data from the SME panel survey show that the reduction in fees of 2013 is perceived as useful or very useful by nearly half of the respondents (46 %), whereas a quarter was not aware of this measure. Similar feedback was given for the Regulation on data sharing.

In some cases, the cost of the registration of substances was a reason for an SME to withdraw from a business line or decide to cease operations. In concrete terms, data from CSES et al (2015) provide a basis for a comparison that shows that SMEs have been experiencing more substance withdrawals than large companies as a result of the 2013 registration deadline[176] and have more often withdrawn substances from the market because of registration costs[177]. According to the study, this effect is linked to the relatively lower capacity of SMEs to absorb the registration costs and the resulting reduced profit margins. Furthermore, the existence of entry barriers for companies in the chemical industry has been raised in the SME Panel by several companies, as well as the fact that some micro and small firms find it increasingly difficult to compete with large companies due to REACH[178].

With regards to the cost of Registration, CSES et al (2015), the average registration costs (per substance per registrant) for the 2013 deadline were found to be 5-25% higher for SMEs than for large companies. Although in general the costs seem to be slightly higher for SMEs, given the large variability of costs it is difficult to draw firm assumptions on the scale of cost difference between SMEs and large companies.

Table 5: Average registration cost per substance per registrant by tonnage band and by size of companies[179]

	>1 000 tpa	**100 - 1 000 tpa**	**10 - 100 tpa**
SMEs	EUR 86 733	EUR 63 723	EUR 73 250
Large companies	EUR 80 619	EUR 88 603	EUR 69 839

There has not been enough experience yet for a full assessment of the impacts of the Authorisation process on SMEs. However, SMEs appear to have been less affected by both the placing of substances on the candidate list[180] and the Authorisation procedure. On the other hand, the SME Panel results indicate that the costs of the application for Authorisation are a concern for approximately one quarter to one third of participating

[176] 36% for SMEs as opposed to 25% for large companies

[177] 47% of SMEs that withdrew substances did it because of registration costs, compared to 35% of large companies

[138] 22% SMEs consider loss of business to big companies as an important indirect cost of REACH

[179] *Source: CSES, 2015, p. 41*

[180] 34% of SMEs have not been affected compared to 17% of large companies in the on-line business (OBS) survey; and 25% of SMEs compared to 42% of large companies in the computer aided telephone interview (CATI) survey

SMEs and broadly similar figures apply to the restriction process[181].

This evidence confirms the conclusions from the 2013 REACH Review Report indicating that compliance costs affected more negatively the business activity of SMEs than of large companies and it is not surprising that concerns remain with regard to the potential loss of smaller businesses and reduction of suppliers both from within and outside the EU/EEA. However, the differences revealed via surveys vary between specific areas of impacts and their extent is rather limited.

6.2.2.2. Support received by duty holders to comply with REACH

As a follow-up to the findings of the 2013 REACH review, the Commission and ECHA enhanced the support and tools made available to REACH duty holders in order to facilitate their understanding and fulfil their legal obligations, focusing on the needs of SMEs.

Over 90% of respondents, across all REACH roles, stated that they used ECHA's supporting instruments. Over half of the respondents found the support 'quite' or 'slightly' useful. Also, the support provided by industry associations is regarded as very useful by the majority of respondents, although some comments from stakeholders criticised the fact that the instruments are not suited for SMEs or even discriminate such market actors, as the solutions often do not reflect the situation of such companies.

The SME panel provides similar indications, as suppliers and helpdesks are the most common source of information. When considering the mechanisms put in place to support companies, the information published by ECHA is seen as the most useful for all sort of companies, closely followed by sector specific information and information published on national, local or regional level.

6.2.2.3. Impact of compliance cost on different sectors and subsectors of the chemical industry and on downstream users

While Registration costs are primarily borne by the chemicals industry (manufactures and importers of chemicals), the Authorisation process and the obligations to pass on information on SVHC in articles have mainly impacted the downstream users. Since the ability of chemicals producers to pass through the registration costs to customers is generally low[182], the larger part of them had to be absorbed by the chemical industry. However, since the chemicals market is segmented and a highly diverse group of enterprises and downstream users participate in market activities, the implementation of REACH affected different parts of the market in different ways.

The feedback to the public consultation indicates that the sectors perceiving the impacts of REACH include a large number of downstream industries such as metals, automotive and mechanical engineering and consumer product industries (textile, plastics, pharmaceutical products and electronics), all of which depend on the use of chemicals.

[181] The preparation of an application for authorisation was seen as a moderately important challenge by 13% of participants and as a very important challenge by 19%. Costs associated with the application were moderately important for 10% of respondents and very important for further 15%. The costs of the Restriction were moderately important for 20% of the respondents and very important for further 17%

[182] The ability of passing through costs is rather sector-specific. The generally low ability to pass registration costs to customers was confirmed in the SME Panel Consultation, where 64% respondents stated they were not able to pass on the increase in the costs on customers and 20% only to a small extent

The issues most frequently raised by the downstream sectors concerned the general complexity and administrative burden related to the Authorisation process, as well as to the obligations to communicate information in the supply chain[183]. A few examples provided by Industry during the public consultation also indicate that the uncertainty and recurring costs associated with the Authorisation process have been an important factor for decisions on whether to locate the manufacture of certain products in the EU or not.

The SME panel indicated additional challenges such as the complexity of the Regulation, the communication of information in the supply chain and the access to data, which seem to have a significant impact on companies, regardless of their type, size or sector. When looking at differences based on the role under REACH, distributors, importers, only representatives and suppliers of articles generally score these challenges higher than other stakeholders. On the other hand, downstream users systematically score the different challenges lower than average (with the exception of the requirements regarding substances in articles). Those challenges are bigger for micro-enterprises. No major differences were found between sectors.

6.2.2.4. Conclusion

The registration costs may be somewhat higher for SMEs than for large companies, particularly for lower tonnage bands, which indicate that the registration costs might be high for SMEs in the last registration deadline in 2018[184]. SMEs' business activity has generally been more affected than large companies' because SMEs have experienced more substance withdrawals[185].

However, since the differences revealed via surveys are relatively limited and the extent of these differences varies between studies, the observed effects do not allow for a firm conclusion.

The support provided to SMEs at national, EU and industry sector levels is seen as useful by a majority of small companies and to a certain extent have helped compensate their lower capacity to absorb compliance costs. However, the feedback from SMEs also suggests that there is still room to facilitate compliance with REACH for small firms for example by providing more practical and user-friendly guidance from authorities, more seminars on REACH and better availability of information in national languages. With regards to the sectorial aspect, since the mechanisms to control SVHC affect the whole manufacturing value chains, and in absence of robust statistical data, any statement of disproportionality of impacts for individual sectors would also be premature.

[183] Out of the 153 statements submitted in the framework of the open questions which can be deemed relevant to efficiency of REACH implementation, 43 concerned streamlining of the authorisation procedure and 110 complexity of the Regulation and information requirements

[184] The findings from CSES 2015 report show that specific cost elements appear to be higher for SMEs which can be explained by lower experience and lower know-how among SMEs with respect to collecting data. In addition , the recent estimates point to potential high costs, specifically for the 10-100 tonnage

[185] According to CSES at all (2015), SMEs reported in a survey experiencing a higher level of substance withdrawal than large firms as a result of the 2013 registration requirements (36% as opposed to 25%)/ More information in Annex 5

6.2.3. WHAT ARE THE COSTS FOR PUBLIC AUTHORITIES?

Assessment question: How are costs distributed among public authorities at EU and national levels?

ECHA's fees collected (2007 and 2016) amounted to EUR 581 million. In addition, the EU budget subsidy has amounted to EUR 225 million, slightly below the expectations due to higher than anticipated fees and charges revenues. Member States' participation in the REACH processes activities has increased, although some processes still appear to be driven by a small number of Member States and a few Competent Authorities do not have the resources to participate in all activities/committees.

6.2.3.1. EU level costs

Between 2007 and 2016, ECHA's budget for REACH amounted to EUR 757 million and the fees collected by ECHA amounted to EUR 581 million, which is above the forecasted fees and charges income for the same period (EUR 509 million)[186]. The cost of ECHA in terms of EU budget (i.e. subsidy) has amounted to EUR 225 million, slightly below the expectations in the 2006 Legal Financial Statement. This difference is mainly due to higher than expected fees and charges revenues.

It is worth noting that the fees collected by ECHA should already be included in the estimates of costs for the different processes, such as registration. Fees and charges were received not only from EU companies but also from companies outside the EU as, for example, half the registrations relate to substances manufactured outside the EU.

ECHA has 517 staff working on REACH and CLP and the Commission services in charge of REACH implementation consist of two units in two different DGs with a total involvement of 35 staff.

6.2.3.2. Member States' direct costs

Direct costs for public authorities include staff and operating costs linked to the management of the registration system, dossier and substance evaluation, management and/or participation in the different committees, preparation of Annex XV restriction dossiers and responding to comments from the public consultation, preparation of Annex XV SVHC identification dossiers, preparation of guidance documents, and publication, communication of information and awareness raising activities, organisation of capacity building workshops and seminars, operation of the helpdesks, IT tools and translation.

The resources devoted to the national level activities such as enforcement or those related to advice to companies (e.g. through National Helpdesks, awareness raising activities) depend on the size of the (chemical) industry in the Member State, the administrative capacity and the enforcement strategies. Regarding the costs incurred by national Competent Authorities (CAs)[187] very little information is available in the 2015 Member States' reports[188]. Those provided have large variations[189], resulting from a combination

[186] 2006 Revised Legislative Financial Statement – SEC(2006)924 2006 Revised Legislative Financial Statement – SEC(2006)924

[187] Understood as Member States and EEA countries

[188] Member States Reports on the operation of REACH (Article 117(1)), June 2015

of differences in resources devoted to REACH implementation, but also from a different understanding of the figures to be reported[190]. Only 6 CAs provided a quantitative estimate of their annual budget for substance evaluation (which ranges from EUR 35 000 in Portugal to around EUR 480 000 in Sweden). 6 CAs provided quantitative data on their resources dedicated to SVHC identification, either the annual budget, full-time equivalents (FTEs), person-days, or number of staff. This does not make it possible to provide an average cost of these different activities. It should however be underlined that several CAs expressed concerns about the burdens and costs of developing restriction proposals due to the non-availability of specific expertise within the Member States. Overall, with some exceptions, the level of satisfaction of CAs with the financial and human resources they can dedicate to REACH is generally relatively low.

Member States also participate in ECHA bodies Member States Committee (MSC), Risk Assessment Committee (RAC), Socio-Economic Committee (SEAC), Forum), in EU level activities such as evaluation (decision-making but also in the manual screening for prioritisation of evaluation under the integrated regulatory strategy), implementation of the SVHC roadmap (in particular conducting RMOAs), or proposals for SVHC identification and restrictions as well as in the CARACAL and the REACH Committee.

The participation and the resources invested by Member States in ECHA Committees has significantly improved in comparison with the first years of implementation of REACH (ECHA, 2016); nonetheless, some Member States still find the high workload required by the Committees challenging, especially the Forum, RAC and SEAC.

The participation of Member States in substance evaluation activities has been increasing over the last years and 22 Member States and Norway have completed at least one substance evaluation. However, until 2014 substance evaluation was mostly carried out by a relatively small number of Member States (6 Member States have evaluated 60% of the substances). This may be due to the relative size of the EU chemicals industry in these 6 countries[191]. When asked about the difficulties encountered in substance evaluation, few CAs complained about the lack of human and financial resources, or the lack of scientific expertise. However, CAs generally mentioned that the fees transferred from ECHA for evaluation did not cover their expenses, and that the situation might worsen since they anticipate an increase of resources dedicated to substance evaluation in the coming years.

About two-thirds of the CAs are now actively involved in the different activities linked to the SVHC Roadmap and this number is increasing (ECHA, 2016)[192]. As regards restrictions, only 8 Member States and Norway have been involved in the preparation of Annex XV dossiers for restrictions, as this is considered a resource-intensive activity[193].

Moreover, the Authorisation process needs to be seen from a broader perspective, which

[189] For example, the figures reported by Member States for persons-day dedicated per year to dossier evaluation vary from 0.02 to 1 000 and the figures for substances evaluated (2012-2014) from 0 to 18

[190] Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting, Milieu, April 2016

[191] There are no obligatory quotas for Member State participation in substance evaluation. It was expected that the numbers would be roughly proportional to the regulatory capacity of each Member State.

[192] For further details, please see Annex 4 – part on Authorisation

[193] For further details, please see Annex 4 – part on Restriction

includes not just the actual process of applying for an authorisation, but the whole preceding process starting with Member States Competent Authorities or ECHA proposing substances for SVHC identification, the inclusion in the Candidate List, and the inclusion of substances in Annex XIV (list of substances subject to authorisation), all of which are drivers of costs for duty holders.

Furthermore, the non-compliance of registration dossiers increases the overall costs. ECHA needs to invest additional resources to check the dossiers and request further information from registrants. Member States need to invest resources for substance evaluation and for obtaining data needed for regulatory measures such as authorisation and restrictions.

6.2.3.3. Enforcement costs

Enforcement costs include staff and operating costs linked to enforcement, inspections, investigation or monitoring. More specifically, according to CSES et al (2015) these costs can include one-off adaptation costs (costs of recruiting and/or retraining staff and purchase equipment to adapt to the new regulation), information costs and administrative burdens (costs of gathering and collecting information needed to effectively monitor compliance), monitoring costs (costs of monitoring compliance with the legislation e.g. border checks collecting statistics, etc.), pure enforcement costs (costs of running inspections, investigations, processing sanctions, handling complaints etc.), and adjudication/litigation costs (costs of using the legal system or an alternative dispute resolution mechanism, to solve controversies generated by the legal rule).

No relevant data have been provided by CAs in the 2015 Member States' reports. Only Ireland provided an estimate of the annual budget allocated. 12 CAs indicated that it was impossible to provide an estimate of the annual budget dedicated to REACH enforcement since it is not separated from other activities of the National Enforcement Authorities. 15 Member States provided an estimate of the time dedicated to the enforcement of REACH. The data submitted is however rather heterogeneous (expressed in number of staff, FTEs, man-year etc.) and does not provide a clear picture of time spent on enforcement of REACH across the EU[194].

6.2.3.4. Conclusion

Information is available about the cost to run ECHA: ECHA's budget for REACH amounted to EUR 757 million and the fees collected by ECHA amounted to EUR 581 million so far. The EU budget subsidy has amounted to EUR 225 million, slightly below the expectations due to higher than expected fees and charges revenues.

There is little data on costs incurred by national CAs but Member States' participation in the REACH processes activities has increased, although some processes still appear to be driven by a small number of Member States and a few CAs claim not to have the resources to participate in all activities/committees. The level of satisfaction of CAs with the financial and human resources they can dedicate to REACH is generally relatively low.

Most REACH activities done by all EU actors are supported by IT systems developed or made available by ECHA, which represents a cost for EU authorities. But at the same time, this provides large economies of scale at EU level, compared to a situation where

[194] Differences in data provided are too large to allow for a meaningful extrapolation

every Member State would need to do it separately, which redounds to increased efficiency.

6.2.4. WHAT WORKS WELL, WHAT CAN BE IMPROVED?

Assessment question: What aspects of REACH (including procedural aspects) are the most efficient and what are the least efficient (including the development of scientific opinions, work of scientific committees, urgency procedures, etc.)? Are there case studies demonstrating highly efficient or inefficient working of REACH processes?

There is evidence of efficiency gains in all the REACH processes since the 2013 REACH Review. Some margin for further simplification has been identified in several areas though, namely in relation to the information requirements, the extended Safety Data Sheets, the process to apply for authorisation and the requirements for substances in articles.

6.2.4.1. Efficiency of the implementation of the REACH processes

As reported in Section 5 (and further detailed in Annex 4), there are a number of ongoing actions by the Commission and ECHA to improve efficiency both in terms of improving effectiveness and simplifying processes. These ongoing efforts reflect the experiences gained with REACH over the past years, and continued discussion between the Commission, ECHA, Competent Authorities and stakeholders.

Registration

The majority of companies respect the '*one substance, one registration*' (OSOR) principle, which improves efficiency for all actors due to the sharing of data. The Implementation Regulation on joint submission of data and data sharing has further strengthened the OSOR principle and has made a major contribution to the avoidance of unnecessary testing, thus resulting in a reduction of the burden on companies. Also, there is some evidence that the guidelines and the ongoing initiatives by ECHA to standardise the information requirements, such as the setting of templates or the definition of a roadmap for the 2018 registration deadline[195], have been appreciated by duty holders.[196]

Furthermore, several solutions have been developed to increase the efficiency of the registration of complex substances. Indeed, the experience so far indicates that while the requirements can be well complied with for concrete, individual substances, industry is facing difficulties in sufficiently identifying more complex substances (e.g. substances of unknown or variable composition (UVCBs)), with a risk of wrongly assessing substance sameness, preparing inappropriate justifications for read-across and not ensuring that adequate hazard data are submitted for their substance. To address these difficulties, ECHA has developed the Substance Identity Profile, which describes the scope of the substance in joint registration dossiers and helps understand whether the joint dossier is indeed for the same substance, adapting the IT systems (e.g. IUCLID) accordingly. Also, ECHA together with the Commission, have helped sectors facing particular difficulties in the registration of their substances by providing them with specific guidance e.g.

[195] ECHA's REACH 2018 roadmap, European Chemicals Agency (ECHA), January 2015

[196] Report of the SME panel

essential oils, hydrocarbon solvents, inorganic pigments, biofuels.

An issue that still needs to be addressed is the information on substances used in articles. Currently this is often limited and not adequate to assess the risk arising from these uses in the different stages of the article life cycle. The main problems encountered relate to the descriptions of uses, and to the assessment of exposure and risks arising from articles.

Other ongoing efforts to improve the registration process include:

- Work is also ongoing for the amendment of Annexes to the REACH Regulation to clarify the registration requirements for nanoforms of substances;
- A system for the possible registration of polymers of concern for human health and/or environment is being investigated;
- The standard information requirements for 1 – 10 t substances or obliging the Chemical Safety Report for the CMR 1A or 1B substances is being studied further;
- In the light of data-sharing obligations that will continue to apply for registration and evaluation, the consequences of the time limitation of the obligation for SIEFs to stay operational until 1 June 2018, as stated in Article 29 of REACH will be investigated further.

The Commission is also supporting the development of alternative test methods, for example through the Framework Programme for Research and the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM). It has also amended the standard information requirements and so reduced or replaced testing on vertebrate animals, such as the requirement for the extended one-generation reproductive toxicity study (EOGRTS). New (alternative) test methods are included in Regulation (EC) No 440/2008, which provides legal clarity and further effort will be made to speed up the process.

Communication of information in the supply chain

There is increasingly efficient supply chain communication due to a better communication up and downstream, which is essential for both improving effectiveness and cutting costs in particular through the harmonisation of description of uses and the exposure scenarios. A number of tools have been put in place to support downstream users in meeting their obligations, especially as regards communication in the supply chain and the development of SDS. These appear to be having a positive effect as highlighted by the work conducted by ECHA and FORUM though specific projects, but could be more fully used. For example, ECHA, Member States and industry actors, including downstream users, supported by their sector organisations are encouraged to:

- Further disseminate and use the tools, templates and guidance provided as a result of ENES and the CSR/ES roadmap,
- Support companies to ensure effective communication in the supply chain
- Make exposure scenario information readily usable on-site, including for SMEs.
- Industry actors are further encouraged to check the content of extended SDS to ensure they contain all the necessary and relevant information
- The products developed by downstream user organisations, such as sector specific use maps should be adopted by the registrants and integrated in their information gathering and assessment processes.

- Collaboration between downstream user associations and ECHA to simplify and harmonise the elaboration of exposure scenarios should be expanded to include new sectors (e.g. building sector).

Further detailed information is provided in Annex 4 part 3.

Actors in the supply chain find it difficult to access information on SVHCs in articles, but more experience is needed to improve this. Likewise, improvements can be seen in the transfer of information to the consumer, and this needs to be better developed reflecting their "right to know".

Another issue that will be further investigated is how to better track chemicals of concern in products, to facilitate recycling and improve the uptake of secondary raw materials, as part of the Circular Economy.

Dossier and substance evaluation

ECHA has been working on improving the efficiency of the processes:

- The Integrated Regulatory Strategy that started in 2014 combines screening for the 'substances that matter' both from an evaluation and a risk management perspective, and focuses the resources on the most relevant information. The development of the Integrated Regulatory Strategy has increased the complementarity and synergy between the REACH processes, as presented in the analysis of the internal coherence of REACH processes below[197]. Its full implementation has only started to deliver in 2016 and cannot be assessed yet, but it is expected to continue to drive efficiency improvements.
- The communication with registrants has been improved to facilitate the assessment of the dossiers.
- Decision and commenting templates, as well as manual of procedures have been put in place.
- Streamlining and optimisation of discussion in Member States Committee (MSC) meetings; anda relatively high proportion of draft decisions still receive Proposals for Amendment (PfAs) from Member States, triggering the involvement of the MSC and associated resources. This number should be reduced, thereby freeing Member States' resources from dossier evaluation to risk management, what could bring more added value overall.

Complementarity and relative timing of the two evaluation processes – compliance check and substance evaluation – when performed on the same substance are also identified as important ways of gaining more efficiency. For example, generic decision to performed substance evaluation only on substances for which dossiers have been previously checked for compliance have in 2017 led to the significant (albeit hopefully transient) effect of the reduction of the number of substances evaluated and thereby postponing the assessment of substances identified as having a concern. Dossier and substance evaluation can operate in parallel, which is beneficial for efficiency and time reasons.

Whilst there are already complementary measures in place and helping, there are others that should be further explored to address the difficulties that still exist in achieving a

[197] See details in the answer to the first coherence question

satisfactory level of compliance in registration dossiers. Further consideration could be given to:

- Supporting registrants in the development of compliant adaptations;
- Registration dossier updates: whether amendments to article 22 of REACH in regard to the situations that trigger mandatory updates, and precise deadlines, are needed;
- Additional clarity in terms of the obligations of registrants having ceased manufacturing could be provided;
- Further improvement of the transparency and dissemination of relevant outcomes;
- Addressing related groups of substances and not only individual substances;
- Running evaluation processes in parallel, with the risk management processes;
- Improving the efficiency of the decision-making process by ECHA;
- Improving the feedback from the evaluation processes to the integrated regulatory approach;
- Risk management action potential may be identified during the initial expert assessment of the registration information in the evaluation and the evaluation decision follow-up;
- The common screening tool for selection and prioritisation should be continuously fed with the experience from the processes applied in order to optimise the screening but also provide better indication of the state of the dossiers in general to enable planning and communication;
- The screening results should help to steer complementary measures;
- Assessing if the full examination process of all testing proposals should continue or could be replaced by a less resource intensive pre-notification procedure or enquiry-type ECHA process.

Member States and Member States Committee members agree that a number of the improvements already in place that will further improve the efficiency of the substance evaluation process. Suggestions to improve the meetings include promoting informal communication and consultation among Member States in the finalisation stage of the substance evaluation process, increasing the use of the written procedure, circulating the documents earlier to enable Member States to consult their experts, and increasing the participation of all Member States in substance evaluation.

Authorisation

a) Implementation of the SVHC roadmap, including RMOA and common screening

Before the implementation of the SVHC Roadmap, the authorities were selecting on their own the substances on which to work, based on different approaches, sometimes leading to double work and not entirely coherent conclusions. All this resulted in a sub-optimal use of the available resources. The implementation of the SVHC Roadmap has improved the authorities' coordination, thus increasing the efficiency, thanks to the common screening approach (selection of substances involving a mass screening performed by the ECHA Secretariat complemented by a manual screening by Member States), and the RMO Assessment (consideration of possible regulatory measures in consultation with others). The common screening and the activities conducted as part of the SVHC

Roadmap also increase the efficiency of the preparation of dossier or substance evaluation decisions, of the Annex XV dossiers for the identification of SVHC or for restriction proposals due to a better knowledge of the substances and their specific hazard and exposure properties.

b) Applications for authorisation

Authorisation being a new process still at the beginning of the learning curve, the general working procedures still have significant margin for improvement. To improve the efficiency of the process, ECHA and the Commission set up a Task Force on the Workability of the Application for Authorisation process in 2014. The Task Force focused on improving the functioning of the whole process. For instance, it foresaw a simplified application for authorisation for the use of substances in low quantities that is expected to lead to a reduction of the workload for ECHA and its scientific committees. The Task Force also prepared a practical guide addressing the most pressing challenges in the authorisation process[198], and supporting documents with recommendations for the definition of the use description within the applications for authorisation[199] and for the drafting of the report following the end of the review period[200].

In the future, close attention will be paid on whether recent efforts to clarify the required information for applications have led to applications of good quality, especially in cases where the applications are to cover many different operators or their uses serve further businesses in the supply chain. Such a development will be key in making the process work more efficiently and, in turn, will make it less controversial to subject new substances to it in the future.

Restriction

The preparation of Annex XV Dossiers is still perceived as an excessive burden by Member States, due in part as well to the lack of specific expertise, namely on socio-economic assessment, the costs associated to their preparation and the high number of requests for additional information from ECHA committees. To streamline and improve the efficiency of the process, a Restriction Efficiency Task Force was set up in 2014. The Task Force delivered 71 recommendations and these have been implemented by Member States, the Risk Assessment and the Socio-economic Analysis Committees and ECHA. A workshop took place in Helsinki in May 2017 that delivered an additional number of recommendations, still to be put in place. Further details are provided in Annex 4 paragraph 7.4.

Application of the '*simplified*' restriction procedure established by Article 68(2) remains a challenge for consumer articles and, so far, against the initial expectations, it has not been more efficient than the normal procedure under Article 68(1). The ongoing proposal concerning CMRs in textiles may provide the Commission services with additional information to improve the efficiency.

Possible further improvements include:

[198] Guidance 'How to apply for authorisation', European Chemicals Agency (ECHA), December 2016

[199] 'How to develop use descriptions in applications for authorisation', European Chemicals Agency (ECHA), June 2017

[200] Note 'Review report of an authorisation', European Chemicals Agency (ECHA), September 2016

- ECHA should act more swiftly in accordance with Article 69(2) and consider the preparation of an restriction dossier (Annex XV dossier) before the sunset date in order to avoid possible distortion of the internal market and penalisation of European producers vis-à-vis non-European producers of (consumer) articles containing such substances;
- The Commission services will assess the possibilities to improve efficiency in the implementation of the restriction procedures in accordance with Articles 68 and 69;
- The need for restriction should be considered in all steps of the implementation of the regulatory strategy (screening, follow-up of the evaluation processes, RMOA) to allow initiation of the restriction work as soon as there is sufficient information available to support the use of this instrument;
- More Member States should get involved (either individually or jointly) in the preparation of restriction dossiers (Annex XV dossier).

6.2.4.2. Other efficiency aspects

IT tools facilitate all REACH processes, and allow processing of high numbers of registration dossiers, fee invoicing and dissemination in a timely and cost efficient manner. IUCLID has enabled the preparation of more than 50,000 registrations, while REACH-IT has processed 10 million dossiers[201] since 2008. According to the information gathered through the external evaluation of ECHA[202], stakeholders indicate overall high levels of user satisfaction with ECHA's scientific IT tools, although improvement possibilities exist (e.g. the complexity and frequency of updates of IT tools is a challenge for duty holders). Nevertheless, the IT investments made over the past years by ECHA are very high and the share of ECHA's expenditure on IT is higher compared to similar agencies such as EMA or EFSA[203] (see further details in Annex 6, part on IT tools).

After a constant investment in IT over 2007 – 2010, the investments made by ECHA in IT progressively increased over the period 2011-2015. In the first years the interface between REACH – IT and IUCLID was changed several times and several of the other IT systems where developed independently. This led ECHA to adopt a multi-annual IT programme to renovate the IT architecture for better maintainability, align IUCLID for stricter control of the quality of submitted data, improve usability and extend automation to cover all regulatory processes not yet served by the IT systems that were in place in 2011, just three years after the start-up of ECHA.

Regarding the development and implementation of the following tools: IUCLID (for dossier preparation), Chesar (for the chemical safety assessment and the generation of CSRs and exposure scenarios for safety data sheets) and REACH IT (bespoke IT systems to perform all the regulatory processes), ECHA spent a total of EUR 18 million for the five years.

[201] Covering classification and labelling notification, pre-registration and registration

[202] Review of the European Chemicals Agency (ECHA) established under Regulation N° 1907/2006, Deloitte, April 2017

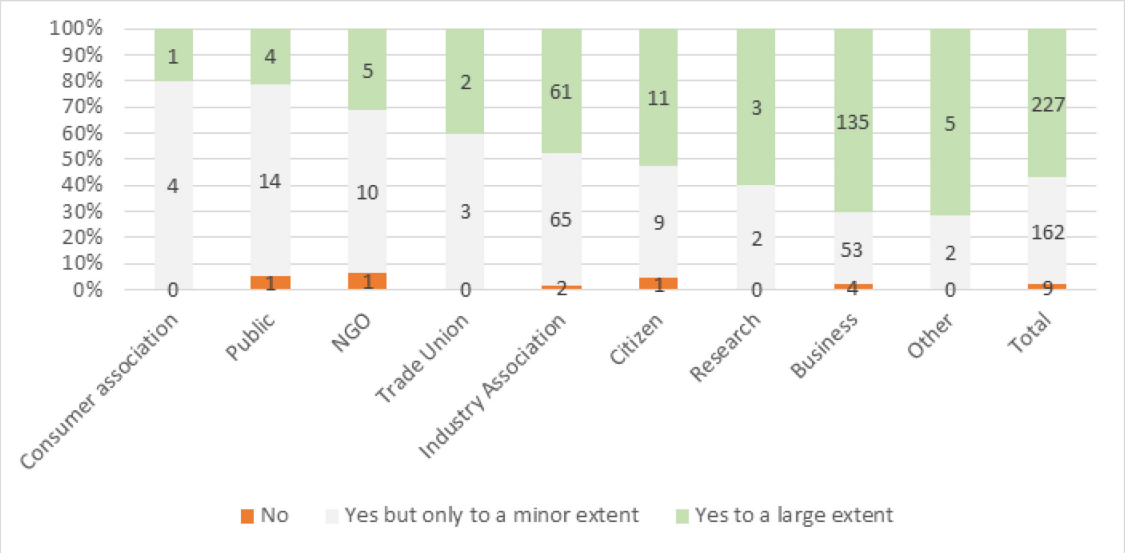
[203] Analysis of the interface between chemicals, products and waste legislation and identification of policy options http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_116_cpw_en.pdf

In consideration of the substantial investment sustained thus far, ECHA needs to have a sound business case for future investments in this area as is already foreseen in the ECHA IT governance model.

6.2.4.3. Stakeholder views on simplification and areas for possible burden reduction

The vast majority of respondents to the open public consultation find that there are areas where the REACH Regulation could be simplified to a certain extent and only a very small share find that it could not be simplified at all. There are large differences between the stakeholder groups, with a majority of respondents from consumer associations, public authorities, NGOs and trade unions on the one side finding that the REACH Regulation could be simplified only to a minor extent – and a majority of respondents from businesses, especially SMES, and from academic institutions finding that it could be simplified to a large extent.

Figure 5: Question 19 of the open public consultation: do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?



Source: Milieu report of the open public consultation in relation to the REACH evaluation, 2017

The main areas suggested for simplification are REACH information requirements and extended SDS, both considered very complex and leading to high administrative burdens, streamlining of the procedure to apply for authorisation and information requirements for substances in articles (Article 33) that should be made more proportionate and easy to understand for companies. Those areas are analysed in further detail in the respective chapter(s) on the implementation state of play, as well as above.

6.2.4.4. Conclusion

Since the 2013 REACH review, mechanisms have been put in place to improve the efficiency of REACH processes as described both above and in more detail in part 6 and Annex 4. This work is ongoing, as experience is gained with the different processes in particular with authorisation and restriction. Overall efficiency of REACH seems to be improving both in terms of improved effectiveness and burden reduction. However, no data is available to quantify those improvements. There is still though room for improvement, for example, to simplify several areas of REACH for duty holders, namely in relation to the information requirements, the extended Safety Data Sheets, the process

to apply for authorisation and the requirements for substances in articles.

6.3. Coherence

6.3.1. IS REACH INTERNALLY COHERENT?

Assessment question: "To what extent are the different work processes, including their output, in REACH interacting in a coherent manner?"

In principle, the different actions under REACH link together well, and they provide for a good flow of information between each other. However, weaknesses exist: for example when registration dossiers do not provide sufficient information or when information flows along the supply chain are insufficient. A number of actions have been taken to make sure that these links are operational, such as the integrated regulatory strategy and the associated common screening process and efforts to improve communication in the supply chain and the development of SDS.

What is the issue?

The Intervention Logic sets out a number of actions that together should deliver results on REACH. This internal coherence question considers the degree to which these actions complement each other and work together or whether there are inconsistencies between them.

REACH is based on the principle that industry takes responsibility for ensuring the safe use of chemicals through the generation of the necessary information for hazard and risk assessment, documentation thereof in registration dossiers and communication of relevant information through the supply chain.

6.3.1.1. Internal coherence

A central point for achieving coherence is the proper information flow from registration to evaluation, to authorisation, to restriction, establishing risk management measures down the supply chain. A number of tools have been developed to ensure that information flow. For example, ECHA has improved the exposure scenarios to help downstream users have a better understanding of the information included in the extended SDS, to better communicate this information up and down the supply chain and to improve the risk management measures in particular from the exposure and the risk of chemicals.

Lack of data in registration dossiers can hinder the good functioning of other REACH processes and identification of the appropriate regulatory measures. ECHA and the Member States ensure internal coherence by checking the information in registration dossiers, and concerns about the adequacy of the hazard, exposure and risk management measures in the registration dossiers may trigger the need for further action by Member States, ECHA or the Commission. In addition, substance evaluation should identify the need for more data in order to clarify initial concerns on risk.

Furthermore, incomplete risk assessments or insufficient risk management measures in registration dossiers may raise concerns regarding the level of risks and therefore lead to considering the introduction of additional risk management measures. The 2013 REACH Review highlighted the need to improve the links between the different risk management measures (i.e. authorisation and restrictions) while the SVHC roadmap established the Regulatory Management Option Assessment as a voluntary process to identify the best

regulatory option. Discussion of the most suitable regulatory action early in the process aims to ensure that different regulatory options can be taken into account when planning regulatory measures. The Regulatory Management Option Assessment helps in deciding whether substances should be subject to authorisation or restriction as its conclusions trigger further follow up to ensure that the substances are regulated under REACH.

The integrated regulatory strategy developed by ECHA brings REACH processes together to improve the achievement of its objectives. Its most relevant elements include:

- Introduction of an enhanced completeness check, including manual screening of dossiers and retroactive screening of dossiers of substances already registered.

- Enhanced support for data input via IUCLID 6, including substance identity profiles, better reporting formats on use and exposure, assessment entity concept.

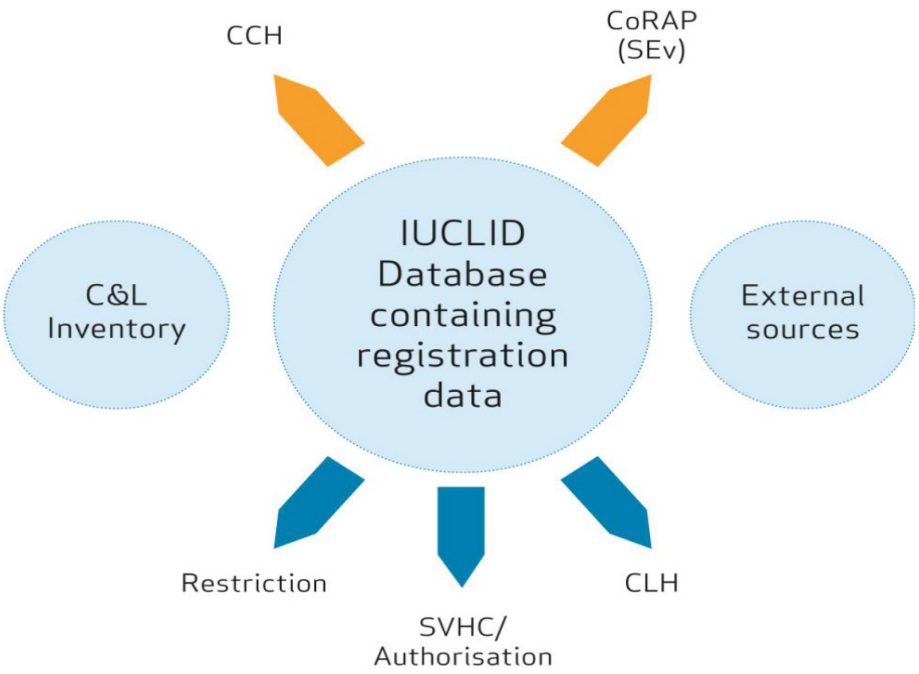
- Grouping approach of substances.

- Improved interplay of dossier and substance evaluation processes, including the possibility of running these in parallel.

In order to support this strategy, ECHA has also developed, in cooperation with Member States, a common screening approach see figure 6 bellow to systematically screen the available information in REACH (and CLP) databases as well as external data sources to identify substances of potential concern and to select these substances for further scrutiny. The common screening approach builds on the experience gained in the implementation of the SVHC roadmap as well as on the early approach to compliance checks, which included the use of algorithms to screen substances for targeted compliance checks. Such screening uses the information concerning hazard properties, exposure and risk management contained in registration dossiers for substances registered above 10 t/y per manufacturer or importer to identify substances for further action.

An example of a group of substances that have undergone the common screening are poly-and perfluoalkyl substances (PFASs). Classification and labelling information for more than 100 PFASs has been notified to ECHA. Among others, PFASs have PBT properties, which made them candidates for regulatory action, e.g. SVHC identification or restriction. As a result of the screening process, two Member States notified their intention to submit a restriction proposal for PFAS poly –and perfluoroalkyl long chain substances.

Figure 6: Screening approach



Regarding information flows along the supply chain, companies are increasingly engaged in the elaboration and transmission of extended safety data sheets (SDSs), resulting in improved communication allowing for safer use of chemicals including complying with the requirements of occupational safety and health legislation. However, information flows do not always work well and in a significant number of cases information is not communicated clearly, leading to inadequate risk management measures. More evidence is reported in Annex 4 paragraph 3.1.2.

6.3.1.2. Stakeholder views

In general, respondents had a fairly positive view of the usefulness of data generated through REACH processes (e.g. registration, evaluation) for public authorities to adopt further risk management measures (e.g. REACH authorisation, REACH restriction). In contrast, and more relevant for the external coherence question, NGO respondents were more critical of the usefulness of data for other legislation (e.g. consumer protection legislation and environmental legislation).

The majority of respondents agreed that the implementation of the SVHC Roadmap, including the Regulatory Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH.

Views were balanced whether the different chapters of REACH are applied in a coherent manner. Some respondents considered that the links between the various REACH processes are not clear and that consistency and integration would have to improve, e.g. to avoid that the same substance is targeted by several parallel processes. Better communication about ongoing processes and coordination among Member States was also called for.

Some noted inconsistencies in the level of evidence required for each procedure and for each topic (identification of the substance, hazards, uses, exposure). Two position papers from NGOs consider that there is a lack of coherence in the way ECHA deals with confidential business information claims: while ECHA checks all such claims as part of

the registration process, it is perceived as more lenient with confidentiality claims in applications for authorisation and for information submitted during public consultations..

One respondent states that the SVHC roadmap is adequate to implement authorisation, but is not adequate for restriction, given that much more information on uses and exposure are needed for restriction, that is however not addressed in the SVHC roadmap, which focuses on Carcinogenic, Mutagenic and toxic for Reproduction/Respiratory sensitiser/ Endocrine disruptors/ Persistent, Bioaccumulative and Toxic hazards.

6.3.1.3. Conclusions

In principle, the different actions under REACH link together well, and provide for a good flow of information between each other. There is a clear and logical sequencing between registration and evaluation and then restrictions, authorisations and the flow of information along the supply chain.

It has to be noted that the information available in the registration dossiers is a bottleneck for the whole process. When the dossiers are not compliant, the information is not sufficient for effective priority setting and to identify the need for appropriate regulatory measures. Despite the progress made there still is room for improving coherence, both between the testing proposal, dossier and substance evaluation activities and between evaluation, restrictions and authorisation. In addition, information flows along the supply chain whilst improving are not always allowing for best use to be made of available information by operators down the supply chain.

A number of actions have been taken to make sure that these links are operational, such as the integrated regulatory strategy. Improved compliance of the registration dossiers, effective implementation of the common screening approach (e.g. by applying more broadly grouping approaches), and using evaluation results to better identify substances that need further regulatory action would increase coherence between the different REACH processes.

6.3.2. IS REACH EXTERNALLY COHERENT?

Assessment question: "To what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?"

REACH is generally coherent with the wide range of Union legislation dealing with chemicals, allowing for synergies and a more coherent chemicals policy overall. Inconsistencies with other legislation (POP, RoHS) highlighted in the 2013 review, where mainly addressed by common understanding papers, which proved to be sufficient for clarify the interface with REACH. However, there are some additional specific aspects which need further clarification for example related to recycled materials to ensure coherence. The Commission is currently working on clarifying the interface with the occupational safety and health legislation, in particular in cases where the same chemicals are regulated under two legislative frameworks.

What is the issue?

The coherence of REACH with other legislation related to chemicals was examined in the 2013 REACH review in the context of the review of the scope of the Regulation. While no major overlaps with other Union legislation were identified, potential or minor overlaps, gaps and synergies with specific EU legislation were highlighted. Building on

the findings of the 2103 REACH review, the Commission has worked to improve the coherence between REACH and other Union legislation on a case-by-case basis, in order to assess the complementarities, synergies and overlaps.

Further elements will be complemented by the ongoing fitness check of chemical legislation.

6.3.2.1. Interface with POPs and RoHS

In 2014, the interfaces between the REACH Regulation and the RoHS Directive[204] and the 'POPs' Regulation[205] were addressed by the Commission services in two Common Understanding Papers[206]. These documents set out practical advice for industry and competent authorities with a view to avoiding conflict or double regulation, and to provide clarity on the specific provisions in the legislation.

The approach taken in these Papers is to examine three scenarios in relation to authorisation and restriction. The scenarios are:

1. a substance is regulated under the other legislative framework before it becomes liable to be regulated under REACH;
2. a substance is already regulated under REACH when it becomes liable to be regulated under the other legislation; and
3. a substance is not yet regulated under either piece of legislation.

The two Papers have become valuable references in the day-to-day management of the relationship between REACH and these pieces of legislation. They have been well received by industry and Member States as they clarified how a chemical substance could be regulated under one legislation or the other, depending on the rationale for the regulatory action and the time when the regulatory process starts.

The REACH/POPs common understanding paper proved helpful in the implementation of the listing of hexabromocyclododecane (HBCDD) under the Stockholm Convention after considering that the REACH authorisation process revealed that the substance has been phased out in EU; and. It also helped in the preparation of restrictions under REACH for decabromodiphenylether (DecaBDE) and for Perfluorooctanoic acid (PFOA) (and related compounds) when these were already in the early stages of the nomination process under the Stockholm Convention. The latter demonstrated that for a substance that potentially fulfils the POP criteria (mainly a substance having vPvB and T properties and the potential for long range transport), carrying out a restriction procedure under REACH is usually a good first step in order to assess the risk to the environment. After the REACH restriction procedure is initiated or completed, it should be followed by an EU POP nomination in order to ensure harmonised risk management measures at the global level and to contribute to the achievement of the World Summit on Sustainable Development (WSSD) political commitment. The outcome of the EU restriction procedure is normally used as a basis to develop the EU position for Conference of the Parties (COP) negotiations on the listing of the substance in the Convention at the COP.

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[204] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**ROHS**)

[205] Regulation (EC) No 850/2004 on persistent organic pollutants (the **'POPs' Regulation**), implementing the obligations of the Union under the Stockholm Convention

[206] http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en

However, experience shows that the extent to which the EU position should be based on the EU restriction depends, i.a. on:

1. The timing of the two procedures, i.e. whether and how long the EU restriction was adopted before the Convention procedure, in particular in relation to the need for possible exemptions;
2. The scope of the EU restriction, in particular if only a limited number of uses were assessed.

The Common Understanding Paper provides guidance in cases where the same substance present in mixtures or articles concerned is potentially regulated in parallel under two different regulatory systems. Assessment of the same information under the two systems can be avoided by using the results of the assessment conducted under one set of legislation under the other legislation according, i.e. an exemption from REACH restrictions or authorisation for substances regulated by RoHS, will avoid double or conflicting rules for the same substance.

The approach set out in the REACH/RoHS common understanding paper proved useful in the restriction on lead and its compounds in consumer articles, excluding electrical and electronic equipment (EEE) already regulated under ROHS. This approach has also been applied in the forthcoming restriction of the phthalates DEHP, BBP, DBP and DIBP, excluding EEE already listed as substances to be restricted under RoHS.

The approach set out in the common understanding paper is expected to provide clarity for the growing market of "smart" objects and the internet of things, when products (e.g. a window, a bag or even clothes) are produced in two versions, one without and one with some added electronic function and thus may fall under two regulatory systems.

The REACH/RoHS paper called for the methodology leading to the inclusion of restricted substances in Annex II to RoHS to be coherent, or even fully aligned, with the methodology set out in Annex I to REACH in particular to cover the manufacturing and use stages of the lifecycle of EEE. This would provide further justification for re-using assessments conducted under one legislation for the other and for exempting EEE from the REACH authorisation requirement and from restrictions. On the other hand, the more similar the two pieces of legislation become, then the less justification there is for keeping them separate in order to avoid potential duplication.

6.3.2.2. Interface with occupational safety and health (OSH) legislation

The interface between REACH and the OSH legislation covers a range of aspects, inter alia the use of information on chemical substances generated and communicated through the supply chain under REACH (e.g. use of Safety Data Sheets, the generation of exposure scenarios and information on exposure control measures), the authorisation and restrictions processes versus the principles of OSH related to risk assessment and risk management, and the enforcement obligations of REACH and OSH national authorities.

The evaluation of the OSH legislation[207] concluded that there are synergies and complementarity between OSH and REACH. It also confirmed a need to further clarify the interface between the two legislative systems in particular to remove any uncertainties and overlaps in their design and practical application.

[207] Link to COM(2017) 12 and SWD(2017) 10 - Ex-post evaluation of the European Union occupational safety and health Directives

A submission via the Commission's REFIT platform[208] (industry and Member States) also sought clarity on the interface between REACH and OSH. The Platform recognised that the two sets of legislation are mutually reinforcing but pointed out that further clarification is needed at their interface.

The Commission shares this analysis and is progressing with work to clarify the interface between REACH and the OSH legislation. This work focuses on the overlap in protecting the health and safety of workers from risks presented by chemicals in the workplace in the context of Derived No Effect Levels (DNEL) under REACH and Occupational Exposure Levels (OEL) under the OSH legislation. A limited number of differences in the methodologies used by the two different scientific Committees (Scientific Committee for Occupational Exposure Levels (SCOEL) and ECHA's Risk Assessment Committee (RAC)) to derive these values have sometimes led to significant divergences, leaving downstream users confused when applying the conditions described in the exposure scenarios attached to the SDS.

In 2015, the Commission, in accordance with Article 95 of REACH (on clarifying conflicts of scientific or technical opinion with other bodies), requested RAC and SCOEL to create a Joint Task Force to analyse and improve the mutual understanding of the different approaches. Both committees were requested to work towards agreed common scientific approaches relating to exposure to chemicals in the workplace, and to prepare a joint report on their scientific evaluation. The Joint Task Force in February 2017 reiterated that differences in the methodologies applied by the two Committees can result in the derivation of different values for the same substance.

In order to avoid discrepancies, the Commission considers that alignment of the two methodologies is required. To reduce potential conflicts of opinion and to ensure at the same time a sound scientific basis to underpin action to improve occupational safety and health, the Commission announced in its Communication on Safer and Healthier Work for All that would request scientific advice from SCOEL or RAC on a case-by-case basis while a more permanent solution was being sought. In March 2017, the Commission services asked RAC to evaluate a number of chemicals in support of the proposals for the 3rd and 4th amendment of the Carcinogens and Mutagens Directive while SCOEL has been so far consulted for the proposal of the 3rd amendment.

The Commission services are considering a Common Understanding Approach clarifying the interface between REACH and the OSH legislation addressing the concerns recognised by the REFIT Platform and proposing concrete steps to remove the overlaps:

- How to use REACH tools (e.g. exposure scenarios, Safety Data Sheets) to enhance the effectiveness of OSH legislation.

- Improve the coordination of national enforcement authorities of REACH and OSH legislation.

- Align methodologies to establish safe levels of exposure to chemicals at the workplace.

- Enhance the role of RAC, involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the Advisory Committee on Health and Safety at Work.

[208] Link to REFIT platform opinion

In relation to the exemption of certain uses (or categories of uses) from authorisation in accordance with Article 58(2) of REACH, the Court of Justice of the EU in Case C-651/15 P VECCO vs Commission confirmed that the OSH legislation does not constitute a specific Union legislation under which, by imposing minimum requirements relating to the protection of human health or the environment for the specific use of a substance, the risk is properly controlled.

Stakeholder views

Stakeholders have repeatedly expressed concerns about a lack of coherence in the implementation of REACH and OSH. A large number of respondents from industry in the replies to the online public consultation confirmed the need for further clarity for the interface between REACH and OSH legislation. NGO and Trade Unions stressed the need for a better coherence and harmonisation between OELs developed under the OSH legislation and the DNELs developed under REACH with a preference to have one single numerical value.

Many respondents from industry suggest that if an EU-wide OEL or a Scientific Committee on Occupational Exposure Limits (SCOEL) recommendation exists, the OELs should replace DNELs and this should be recognised by the REACH authorities as it will avoid double work, conflicts of opinion and confusion at the downstream user level[209].

The respondents acknowledged the work already done by the Commission to improve coherence between REACH and OSH, but call for further efforts to reach consistency between OELs and DNELs, including also a better cooperation and alignment of methodologies of RAC and SCOEL, as this would help to overcome problems in practice.

Many respondents from industry suggested that OSH legislation should be prioritised during the Risk/Regulatory Management Option Analysis[210] (RMOA) when it is determined that a risk is mainly related to the workplace as this would avoid any possible conflict or overlap with the REACH processes such as authorisation and restriction. Since the OSH legislation also contains a substitution requirement, the OSH legislation was considered by some respondents to be an alternative "risk management option" to REACH authorisation. Respondents from industry also considered that if the workplace legislation or the RMOAs identify risk for workers from exposure to a certain substance, then it would not make sense to spend additional resources on the candidate list or authorisation if no additional impact is expected.

Some consider that information generated under REACH should be better used under OSH legislation and, in particular, for information in the safety data sheets (SDS) although some difficulties were found in the extended SDS, which are considered to be unclear and confusing for straightforward application in the workplace.

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[209] Views expressed through the open public consultation - Stakeholder consultation: report of the open public consultation

[210] Originally the RMO stood for risk management options. To avoid confusion with the obligations under Article 69 to prepare an annex XV dossier when a risk has been identified and the obligation in Annex XV to determine the most appropriate Union wide measure to address the identified risk and to better reflect the actual work done, the RMO is now called Regulatory Management Options. Regulatory Management Option (RMO) Assessment is the process for identifying the best regulatory option for a substance. The RMO Analysis is the document presenting the information on the substance, the possible options and the preferred one.

6.3.2.3. Interface with the cosmetic products regulation

In 2014, ECHA and the Commission services presented a joint statement on the interface between REACH and the Cosmetic Products Regulation, which clarifies among other an issue with regard to animal testing. While the Cosmetic Products Regulation bans animal testing and marketing and REACH aims to reduce and eventually fully eliminate animal testing, the testing of cosmetic ingredients on animals may be required as a last resort under certain conditions to meet REACH registration requirements. So far, no actual case has been detected where animal testing was conducted for the purposes of REACH registration on a substance used solely as an ingredient in cosmetics. Nevertheless, following a complaint by an animal welfare NGO, the European Ombudsman opened an inquiry into the matter, concluding that the joint statement is not contrary to the Cosmetics Regulation or to EU law more generally[211].

6.3.2.4. Interface with waste legislation

Activities related to the interface between REACH and the Waste Framework Directive (WFD), focused initially on clarifying when recycled materials cease to be waste and become subject to REACH again. This is significant for the implementation of REACH as "waste" is not within its scope. REACH contains a conditional exemption from certain REACH requirements, including registration of substances "which are recovered" in the EU. However, REACH does not set any specific provisions on how the use of this exemption for recovered substances is to be monitored and a recovery operator who uses the exemption has no explicit obligation in REACH to notify ECHA or the competent authority of a Member State that he is using the exemption.

To tackle this issue, a practical solution could be that the holder of a recovered substance who wishes to use the registration exemption under Article 2(7)(d) of REACH, being a potential registrant, should be required to notify ECHA and his Member State Competent Authority that he considers that the conditions of this exemption are fulfilled. This would facilitate implementation and enforcement of the exemption, in particular as regards the identity of the recovered substances placed on the market which would also facilitate the implementation of a circular economy. Moreover, the Commission is considering if the wording used in the provisions of Article 2(7)(d) is sufficiently clear to ensure that the obligations are fully implemented and enforced.

The implications of certain REACH requirements for the recycling of materials have been discussed in the context of specific restrictions or applications for authorisation e.g. in the case of the traceability of substances of concern in products and recycled materials or the setting of limits for the presence of the substances in recycled materials. One of the actions under the Circular Economy Action Plan aims to address legal, technical or practical problems at the interface between chemicals, products and waste legislation, including how to reduce the presence and improve the tracking of substances of concern in products and the development of a methodology to determine when a material containing substances of concern can be recycled or should rather be disposed of. A

[211] Ombudsman case 1130/2016/JAS, Decision of 21 Jul 2017. In addition, the President of the General Court replied in July 2017 to an individual complaint case that "in so far as the applicant is required by an individual decision from an EU Agency which is addressed to it, in the present case the contested decision, to carry out animal testing, the fact of complying with that requirement cannot result in it incurring liability because of another EU measure of general scope, in the present case the Cosmetics Regulation

roadmap[212] has been published and a Communication setting out various options to tackle these issues is scheduled for the end of 2017.

Stakeholder views

The responses in the open public consultation confirmed the pertinence of the issues above. One business respondent considers that recovery processes will regularly result in the production of useful, resource efficient, but changed, materials that may have properties that do not easily relate to the registered substances from which they were derived.

Respondents from all stakeholder groups consider recycled materials under REACH, as important for the Circular Economy. Several respondents suggest that recycled materials should comply with REACH, like any other materials. One respondent considers that to achieve a truly sustainable and safe circular economy, it must be accepted that not all materials can be reused or recycled, given that they may contain unwanted substances that should not re-enter the market. When a temporary authorisation has been granted to enable the continued presence of hazardous substances in products made from recycled material, the material should be labelled and specifically marked, and the authorisations must be as limited as possible in scope and time.

On the other hand, one industry position paper suggests that to promote recycling rather than landfilling, longer transition periods and phase-out periods for toxic substances included in recycling materials should be allowed, if the related risk or exposure is low. Several industry respondents call for greater coherence between REACH authorisation and the Circular Economy. They suggest that the substance identity principles established in REACH should be consistently and coherently applied throughout registration and authorisation, in particular: a substance present as an impurity that is not deliberately added in a mixture and does not fulfil any function should not be subject to authorisation and unknown or variable composition, complex reaction products or of biological materials (UVCBs) are to be seen as stand-alone substances and must not be decomposed into individual substances for the assessment under REACH.

One government authority considers that the provisions in REACH, such as restriction, authorisation, registration, and information requirements for substances, mixtures and articles are crucial to boost a circular economy.

6.3.2.5. Interface with other Union legislation

Other aspects of the relationship between the REACH and other Union legislation affecting chemicals, which do not constitute an overlap but cases of synergies and complementarities, are being clarified, as described below:

- In relation to Directive 98/83/EC on the quality of water for human consumption, Regulation (EC) No 1935/2004 on food contact materials (FCM) and Council Regulation (EEC) No 315/93 laying down Union procedures for contaminants in food, REACH is considered not to apply to the extent that measures adopted and allowed under these pieces of legislation relate to the protection of human health. REACH still applies in relation to environmental endpoints.

[212] Analysis of the interface between chemicals, products and waste legislation and identification of policy options

- Risk assessment under the legislation on Food Contact Material (FCM) may benefit from information made available during the hazard and risk assessment in a REACH Annex XV dossier or performed under the CLP regulation, and vice-versa. The use of substances listed in Annex XIV in FCM is exempt from REACH authorisation for hazards related to human health, while they remain subject to REACH authorisation with respect to occupational or environmental risks as authorisations under the FCM legislation do not consider occupational or environmental exposures. This means that industry has to apply for authorisation under REACH (occupational and environmental risks).
- Work is ongoing to transfer part of the restriction on ammonium nitrate in entry 58 of Annex XVII to REACH into Regulation (EU) No 98/2013 on the marketing and use of explosives precursors to address the potential criminal use of chemical substances.
- For medicinal products (Regulation (EU) No 726/2004), an information gap exists in relation to the environmental risks related to the manufacturing or formulation stages of medicinal products for human and veterinary use as a result of their exemption from REACH in accordance to Article 2(5). The manufacture of medicinal products involving chemical processes of industrial scale is covered by the Industrial Emission Directive 2010/75/EU (IED) but formulations per se would normally not be covered, except particular cases that involve use of large quantities of solvents. Where the activities are covered by the IED, adequate controls have to be put in place to respect conditions in permits granted regarding emissions to the environment, based on Best Available Techniques (BAT). However it has to be emphasised that the environmental risk assessment is not equivalent to that performed under REACH, notably as the IED does not concern the whole life-cycle of the chemicals after production.
- In relation to Regulation (EC) No 765/2008 on market surveillance, the concept of 'serious risk' applied is not aligned with the risk derived applying the risk assessment methodology under REACH and can cause divergent interpretations among market surveillance authorities.
- Liaison with other enforcement networks should be enhanced and collaboration with other policy sectors increased (e.g. AdCo[213], customs).As it concerns the role of customs in the enforcement of the REACH requirements, the roles and tasks of all actors should be defined more clearly in order to enhance legal certainty for both economic operators and customs authorities. To this effect, regulatory measures in addition to non-legislative means (e.g. guidance, training, pilot projects) could be considered
- In relation to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, a need to align REACH information requirements for physical-chemical properties and CLP classification categories has been identified. A further coordination should be ensured between the decision related to testing proposals/substance Evaluation under REACH and the adequacy of such decision for classification under the CLP.
- In relation to the Biocidal Products Regulation EU No 528/2012, legislative proposals on the approval of an active substance, including measures on treated articles with

[213] Administrative Cooperation Groups for European cooperation on market surveillance.

biocides, has to take into account any existing restriction listed in Annex XVII of REACH in order to avoid possible duplication (ex: creosote and treated wood with creosote), and vice-versa.

- In order to improve the consistency on the exchange of information and the risk assessment between REACH and other Union legislations, when an Annex XV dossier for restriction, addresses the cumulative exposure of humans and emissions to the environment from different sources also in areas not covered by REACH, the specific Union legislation could use the information included in the Annex XV dossier as a basis for further regulatory actions. The Annex XV dossier could indeed be used as an important source of information for other Union legislations.

6.3.2.6. Scientific Committees and EU Agencies

ECHA is required to work with other EU agencies and scientific committees in order to avoid potential conflicts of opinion (Art.95 of REACH); similar requirements apply to other EU agencies (e.g. EFSA) or scientific committees (e.g. SCOEL).

A successful example of such collaboration is the joint evaluation of the most recent scientific literature by EFSA and ECHA during the discussion of the restriction proposal on Bisphenol A where they came to an agreed hazard assessment. Collaboration between scientific committees has been more difficult between RAC and SCOEL, when they were mandated by the responsible Commission services to clarify their divergences in the derivation of a safe exposure limit for the substance N-Methyl-Pyrrolidone (NMP). The two Committees did not manage to reach a common opinion, leading to the setting up of a Joint Task Force between them in order to analyse and if possible agree on their general methodologies for deriving safe or acceptable exposure limits. The two scientific committees so far did not reach a common agreement.

The spirit of cooperation to avoid conflicts of opinion with other scientific bodies, as set out in Article 95 should be further reflected in other EU legislations in order to ensure better consistency between different Scientific Committees operating in the assessment of chemicals, for example related to the classification of active substances used in plant protection products, where divergences have been observed between EFSA and ECHA not necessarily linked to the lack of cooperation between the two Agencies.

The data, methodologies and capacity developed under REACH should be used to support the implementation of other legislation, concerning identification and management of the risk of substances that are within the scope of REACH. ECHA should facilitate access to the data it holds for Scientific Committees of other Agencies or Member States authorities conducting assessments, while safeguarding confidentiality and intellectual properties rights. The overall aim is that ECHA's information, knowledge and competences are increasingly used to support the implementation of other legislation and policy areas related to the safe use of chemicals.

6.3.2.7. Implementation of the SVHC roadmap in relation to other legislation

The RMOA is a voluntary procedure not explicitly envisaged by REACH but recommended to be implemented by the Competent Authorities of Member States and ECHA to analyse all the possible regulatory options for a specific substance or group of substances.

In the context of the online public consultation, a great majority of industry respondents supported the RMOA approach as it improves the coherence between REACH and other

EU legislations, suggesting that it should be more harmonised and that the RMOA process should become binding under REACH. Some industry respondents even proposed to conduct ex-post RMOA for substances already on the candidate list for which this was not done in the past and that as a result substances might be removed from the candidate list.

Other stakeholders (NGOs, consumer associations, trade union, and one industry association) consider that RMOA is not an adequate procedure and should not be binding. Some call for the RMOAs to be abandoned, as they have introduced too much subjectivity and a loss of coherence. They consider that all SVHC should be added to the candidate list and express concern that since the RMOAs were introduced, the number of substances added to the candidate list has significantly decreased, and the process has become costly and burdensome for Member States. In their view, the RMOA process already includes steps upfront (i.e. consideration of use and exposure information) that legally belongs only to the prioritisation or application for authorisation steps. They consider that RMOAs not only hamper the substitution goal and undermine the precautionary principle, but also deny EU consumers their 'right to know'.

The Commission considers that the implementation of the SVHC roadmap and in particular the RMOA has contributed to a more systematic analysis of the regulatory measures available for public authorities for a specific substance. In addition, it improves coordination of Member States and enhanced transparency and involvement of industry. Member States recognise the added value of the RMOA process in identifying the best regulatory approach, either within REACH or through other Union legislation (e.g. CLP Regulation, OSH legislation, etc.).

6.3.2.8. Conclusions

No major incoherencies between REACH and other Union legislation have been identified. There are however some inconsistencies, some of which have already been addressed in the past years, while others are still requiring attention. Common Understanding Papers and Roadmaps help to better clarify specific implementation aspects of the interface of REACH and other EU legislation, increasing transparency and predictability as well as avoiding duplication. The main inconsistencies are:

- The interfaces between REACH and the RoHS Directive and the 'POPs' Regulation were addressed in two Common Understanding Papers, which have provided clarity and led to synergies between the legislation. On the interface between REACH and RoHS there is still the possibility that the same information has to be assessed under two different regulatory systems, in cases where the same substance in the products concerned are regulated under both pieces of legislation. This aspect should be further explored in order to avoid overlaps.
- There is an issue with when recycled materials cease to be waste and become subject to REACH again, which is being tackled in the context of the Circular Economy and the chemicals-products-waste interface.
- Although some synergies can be considered between REACH and OSH, there is an overlap which request efforts to avoid disparities in the way in which different Scientific Committees are calculating DNEL under REACH and OEL under OSH legislation. Steps have been taken to avoid conflicting results, and in the future to improve consistency of scientific methodologies. This disparity between values is a core element when performing the risk assessment and choosing the appropriate risk management measure from the exposure of chemicals at the workplace. Moreover, if

information generated under REACH (e.g. improved risk management measures through authorisation or information in Safety Data Sheets) is better used to comply with the requirements of occupational safety and health legislation, this would ensure a safer use of chemicals at the workplace.

- Where the risk to the safety and health of workers in the workplace is not (or is no longer) adequately controlled by the requirement of the OSH legislation in light of emerging/new scientific information on the severity of the risks arising from occupational exposures or new developments in exposure control technologies, additional regulatory actions such as a restriction or authorisation under REACH may be the appropriate risk management measure.

More generally, efforts are being made to ensure that ECHA's information, knowledge and competences are increasingly used to support the implementation of other legislation related to the safe use of chemicals.

6.3.3. IS REACH INTERNATIONALLY COHERENT?

Assessment question: "To what extent is REACH coherent with international efforts, or chemical legislation in third countries?"

In terms of policy objectives, REACH is coherent with chemicals policy in third countries. REACH has some differences from the actual regulatory regimes to implement these policy objectives, but this does not necessarily mean they are incoherent and in fact there seems to be some signs of harmonisation. A number of the tools used in REACH implementation have been developed at the OECD and are coherent with other countries legislation, when the same tool is being utilised.

What is the issue?

Coherence with international chemicals efforts can be measured on three levels:

- Policy objectives
- Legislative requirements
- Tools used to implement legislative requirements.

6.3.3.1. International Coherence

The 2013 REACH review summarises the Commission cooperation with the OECD (e.g. development of IUCLID, eChemPortal, QSAR Toolbox) and with third countries (e.g. meetings and workshops to inform them about REACH implementation, extended bilateral scientific and technical cooperation). The 2013 review did not include information on coherence and differences between REACH and related international efforts or on chemical legislation in third countries specifically.

6.3.3.2. Policy objectives

REACH was designed as the EUs contribution to meeting the World Summit of Sustainable Development 2020 chemicals goal and its implementation in the EU which aims to achieve that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects to human health and the environment. As mentioned earlier, this goal is now included as target 4 in Sustainable Development Goal

12. There is therefore an overarching, internationally accepted, policy objective regarding chemicals shared by all countries, including the EU and its Member States.

The chemical management cooperation framework set up under the United Nations Strategic Approach to Chemicals Management (SAICM) is actively supported by the EU and its Member States. This approach provides the international platform for achieving the 2020 goal.

The way in which the EU implements this over-arching policy objective is through the objectives of REACH (protection of human health and the environment, ensuring the well-functioning of the internal market, enhancing competitiveness and innovation and promotion of non-animal methods). These policy objectives are shared by some third countries (e.g., Canada, US).

6.3.3.3. Legislative requirements

The EU implements in separate pieces of legislation the Rotterdam and Stockholm conventions through the respective Prior Informed Consent (PIC) which require notification to the Countries importing hazardous chemicals and POP regulations[214]. The international coherence between REACH and the Stockholm convention work at EU level is discussed above concluding that the interaction functions well.

The EU implements almost completely the United Nations Globally Harmonised System (GHS) for classification and labelling of chemicals in the CLP regulation no 1272/2008. Many other countries have implemented GHS too, although not always as comprehensively as the EU. Hence there is an increasing coherence between other countries implementation of the GHS and that of the EU which allow a better exchange on hazard properties of chemicals e.g. in import and export.

The interaction between REACH and chemicals legislation of the main EU trading partners is discussed in the effectiveness section concluding that the legislation is often different, but most have similarities with REACH. For example the new Toxic Substances Control Act (TSCA) of the U.S. has some similarities with REACH Restrictions system although do not cover the wide spectrum of hazardous chemicals as it is mainly based on priority lists of chemicals whereas REACH assess all the registered chemicals. Several third countries have adopted registration systems similar to the EU's REACH; however , in most cases, these regimes are limited to new substances e.g. substances already on the market are not evaluated.

Overall, however, there is world-wide not one single standard which drives the development of chemicals management systems and hence most systems are tailor made to their own context, although harmonisation efforts are taking place on a global scale through e.g. GHS and the WSSD goal. In this picture, REACH is the most advanced and comprehensive chemical legislation.

In spite of the increasing international harmonisation of chemicals legislation, convergence of legal requirements in different jurisdictions is still limited. One of the main difficulties is the lack of mutual recognition of testing results in particular by non-OECD countries that do not adhere to the mutual acceptance of data such as China.

[214] Respectively, Regulation (EU) 649/2012 and Regulation (EC) No 850/2004

6.3.3.4. Tools used to implement legislative requirements

The EU and its Member States are active in contributing to the technical and scientific harmonisation and standard setting done at OECD. These include:

- Test Guidelines;
- Harmonised templates for reporting data, e.g., from OECD Test Guidelines;
- International Uniform ChemicaL Information Database (IUCLID), for entering, storing and searching data electronically in the format of the OECD harmonised templates;
- eChemPortal, as a one stop portal to access disseminated data in locally stored databases with a direct access to IUCLID databases;
- Guidelines for exposure and hazard assessment
- Guidelines for use of alternative data
- QSAR Toolbox, used to estimate chemical hazards by grouping chemicals and filling gaps in (eco) toxicity data
- Adverse Outcome Pathways

All these tools are used to fulfil REACH requirements. The EU and its Member States contribute to their development directly through the OECD. Thus, the OECD does present a very efficient mechanism for developing the tools the EU needs for the implementation of REACH and CLP, and also ensures immediate international acceptance in all OECD countries. In particular, as testing of chemicals is labour-intensive, expensive and often requires animals, the OECD test guidelines implemented in the EU via the Test method Regulation allow the mutual acceptance of data, i.e. test data generated in any OECD member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.

These tools are also available via the OECD Internet-based Toolbox for Decision Making in Chemicals Management (IOMC) to countries using the tool box to develop chemical management systems.

6.3.3.5. Stakeholder views

There were limited comments received concerning coherence with international efforts specifically. However, some stakeholders responding to the open public consultation indicated that one of the unintended benefits of REACH is that it has become a benchmark for chemicals regulations in the world, either because REACH has inspired the adoption of similar legislation in other countries, or has become a global source of information on chemicals promoting innovation and/or safe use of chemicals worldwide. These stakeholders were mostly industry associations and NGOs. Therefore there are some indications that REACH is inspiring coherence internationally for chemical legislation.

6.3.3.6. Conclusions

In terms of policy objectives, REACH contributes to internationally accepted policy objective regarding chemicals shared by all countries, including the EU and its Member States in the form of target 4 in Sustainable Development Goal 12.

There are a number of different regulatory regimes globally. These all have their differences in terms of principles, approaches and processes but there are indications of harmonisation and certainly they do not appear to be inconsistent.

A number of the tools used in REACH implementation have been developed at the OECD and are coherent with other countries legislation, when the same tool is being utilised. Furthermore, adhering to the WSSD chemical goal in REACH and implementing of GHS in the CLP regulation, which is used for a number of regulatory processes, further strengthens coherence. In addition, the EU and its Member States are active and significant contributors to the international chemicals work, thereby enabling a more consistent approach to chemicals management around the world.

6.4. Relevance

6.4.1. IS REACH TECHNICALLY RELEVANT?

Assessment question: "To what extent is REACH capable of adapting to evolving needs (e.g. through adaptations to technical and scientific progress)?"

REACH has been largely capable of adapting to evolving needs in a context of scientific advances and technical progress. Two issues that will merit further investigation are the review of registration requirements for low tonnage substances and the need to register polymers which were addressed in the REACH review 2013 but not yet clarified. With regards to testing methods, the update mechanisms of REACH are working but the need to manage a complex process means they are judged to be slow. With regards to nanomaterials, there is an ongoing action to improve how to deal with them. Efforts are also ongoing to improve the identification of endocrine disruptors.

What is the issue?

Scientific knowledge on chemical substances and testing methods has been continuously evolving since before the adoption of REACH. In parallel, new substances have been manufactured and registered under REACH, possibly raising new concerns and risks to human health and the environment. Since REACH has to work in this evolving context it is important to ensure that it adapts to this changing environment quickly and efficiently. The REACH review 2013 highlighted a number of specific issues, in particular for substances between 1 and 10 tonnes per year (especially CMRs); polymers; testing methods; and nanomaterials. The present review identified other emerging issues, such as endocrine disruptors and combination effects of chemicals.

6.4.1.1. Technical relevance

Review of the registration requirements for low tonnage (1-10 tonnes/year) substances

Based on the recommendations from the REACH Review 2013, studies[215] were launched on whether to extend the requirement for chemical safety assessments and chemical

[215] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year, RPA, March 2015. http://ec.europa.eu/environment/chemicals/reach/publications_en.htm

safety reports to CMR 1A/1B substances below 10 tonnes[216] and to modify the minimum standard information requirements for substances produced at 1-10 tonnes[217].

With regards to the level of protection of human health and the environment, all the options assessed offer higher levels of protection than the current requirements (as they improve information). The cost analysis of the different options concluded that all of the options would provide an increased benefits/costs ratio and also improve cost-effectiveness compared to the current requirements for registration in 2018. However, there were affordability concerns for the increased information requirements, especially given the number of SMEs who might be affected.

As a follow-up to the recommendation in the *General Report on REACH* 2013, the current 1-10 tonnes requirements will be further examined taking advantage of the experience gained with the last registration deadline of 2018 either to increase the testing requirement for the registrant to update their dossier and/or to increase the information requirements for new registrations.

Review of the need to register polymers

Polymers are exempted from registration under REACH[218] but the Regulation includes a review clause saying that the European Commission may present, as soon as a practicable and cost-efficient way of selecting polymers for registration can be established, a legislative proposal aiming at registering a range of selected polymers[219]. As a follow up of the REACH review 2013, a study on the registration requirements for polymers[220] assessed two strategies: grouping polymers for registration; and, defining a category or categories of polymers of low concern adopted in non-EU jurisdictions (i.e. Australia, USA, Canada, China, Japan, New Zealand, Philippines, South Korea, Taiwan).

This study concluded that a majority of the studied countries have a 'polymers of low concern' categorisation or a grouping approach or both for new polymers in line with the respective OECD definition. Polymers categorised as of low concern are considered less hazardous and benefit from reduced requirements. However, the study did not provide enough information on how to identify polymers of concern for human health and/or environment and how to group them. The Commission services will further investigate, and details will be set out in a Roadmap.

Testing methods

Timely amendments of the testing methods under the Test Method Regulation[221] , and in particular of the REACH information requirements are important to ensure that scientific development is taken into account under REACH. REACH Annexes VII to X as well as the Test Method Regulation have been amended respectively 3 and 4 times during the reporting period to reflect scientific and technical progress, in particular in relation to alternative methods (see Annex 4, section on testing methods for further details).

[216] According to Article 138(1)
[217] According to Article 138(3)
[218] Article 2 (3) of REACH, however according to Article 6 (3), the monomer has to be registered under specific conditions.
[219] See Article 138(2) of REACH
[220] Technical assistance related to the review of REACH with regard to the registration requirements on polymer, Bio by Deloitte et al, February 2015
[221] Regulation (EC) No 440/2008

Animal welfare NGOs criticised in the public consultation long delays for the update of REACH information requirements and the Test Methods Regulation after the adoption of new OECD test guidelines. However, the implementation of a new method in the information requirements often requires consideration of its role in the overall safety assessment framework and thus additional technical and regulatory discussion with MS and stakeholders, especially where OECD test guidelines give flexibility in the study design or provide results that needs to be integrated with other information to address REACH information requirements. The timely formal recognition of new methods agreed as OECD test guidelines through their inclusion in Test Method Regulation remains a logistic challenge due to the inherent administrative processes and the time required for adaptation to EU standards and translation of the long and highly technical test protocols in all EU languages. The possibility to publish the test protocol in English only should be assessed and discussed with Member States.

It should be noted that the impact of this prolonged process is alleviated by ECHA providing up-to-date information about the availability and possible use of test methods for the purpose of REACH also before their inclusion in the Test Method Regulation.

6.4.1.2. Other issues

Nanomaterials

The amount of specific information about nanomaterials (substances in nanoform) in REACH registration dossiers is insufficient to ensure that registration data is actually relevant and covers the nanoforms of a registered substance. This is to a large degree due to the fact that REACH does not explicitly require registrants to provide separate information for forms of a substance, including bulk form and different nanoform(s).

Furthermore, REACH does not contain a definition of nanomaterial / nanoform.

The ongoing revision of the REACH Annexes for nanoforms is addressing this shortcoming. The changes address the documentation of different nanoforms, the relevance (and where necessary generation) of hazard and exposure information, as well as the assessment of the specificities that might occur through their transformation in the environment or by the modifications made by downstream users for their applications.

One of the characteristics of nanomaterials is the ability to modify function through structure (size, shape, surface chemistry of particles).

Some IT tools, grouping and read-across approach, as well as supporting instruments (e.g. modelling) will have to be extensively applied and require further development and validation in order to cover these additional characteristics.

Substances with endocrine disrupting properties

REACH considers the potential for endocrine disrupting properties to be one of several factors when prioritising substances to be assessed for regulatory risk management[222].

As part of the implementation of the SVHC Roadmap 2020, ECHA and Member States are making a determined effort to identify all relevant endocrine disruptors (EDs) of equivalent level of concern by 2020[223]. REACH provides suitable tools to identify EDs using the WHO/IPCS (2002) definition and to regulate such substances.

[222] As referred under the effectiveness section

[223] Seven substances or groups of substances (4-(1,1,3,3-tetramethylbutyl)phenol (also known as 4-tert-octylphenol) and 4-nonylphenol, 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated and 4-nonylphenol

However, experience in the SVHC identification process revealed that there are two challenges for the identification of EDs as SVHCs:

1) whether the substance is of equivalent level of concern[224];

2) The availability of relevant scientific data[225] to identify substances using the WHO/IPCS (2002) definition. The REACH standard information requirements have limited capacity for providing data on endocrine disrupting properties: a number of adverse effects related to ED mode of actions (human health and environmental) are specifically identified by the extended one-generation reproduction toxicity study (EOGRTS), as well as by some of the other information requirements

However, the tests required still do not include the endpoints relevant for endocrine disrupting properties or they are only optional. This suggests that a better integration is needed of the latest developments on test methods and screening strategies to better identify endocrine disrupting properties.

The constantly developing scientific comprehension of endocrine disruption stresses the need for continuous knowledge exchange between regulators and the scientific community. The Commission supports this, for instance, by organising a workshop in cooperation with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)[226] on how to assess disruption of the thyroid pathway and on the interpretation of test observations. There is a need for a more systematic exchange of knowledge across disciplines, mainly between regulatory experts and scientists.

Finally, despite the progress under the OECD test guideline programme, gaps remain for an effective identification of endocrine disruptors. For this reason the Commission has stepped up its efforts to support test method development related to endocrine disruption by funding several projects and scoping workshops[227,228,229]. These test methods are also key for the identification of substances with endocrine disrupting properties used in biocidal products or plant protection products. The Commission recently adopted a Regulation setting scientific criteria to identify substances with endocrine disrupting properties used in biocidal products. A draft Commission Regulation setting criteria for determining endocrine disrupting properties of substances used in plant protection products is still under scrutiny of the European Parliament and the Council until 9 April 2018 . For the implementation of the criteria two EU agencies, the European Food Safety Agency and the European Chemicals Agency, are developing joint scientific guidance.

Combination effects of chemicals

REACH provides mainly information on substances on its own, however partially addresses combined exposure from a single chemical (i.e. aggregate exposure) since

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ethoxylated) have been identified as SVHCs and placed on the candidate list[223] due to endocrine disrupting properties.

[224] As it refers to article 57 (f) of REACH

[225] Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products. COM (2016) 350 final

[226] Workshop on thyroid disruption

[227] Supporting development of the OECD Detailed Review Paper on the Retinoid System

[228] Review of temporal aspects in the testing of chemicals for endocrine disrupting effects

[229] Workshop on setting priorities for further development and validation of test methods and testing approaches for evaluating endocrine disruptors

registrants are required to perform risk characterisation for combined routes of exposure (oral, dermal and inhalation). However, a registrant is not obliged to take into account an exposure to the same substance from activities from other producers or importers.

Although REACH does not explicitly cover risk assessment from combined exposure to multiple chemicals, in specific cases (i.e. phthalates and tattoo inks) during the Restriction process and during Substance Evaluation, combined exposure to multiple chemicals from multiple sources can be considered. For instance, restriction proposals may take into account the combined risk arising from several substances with similar mode of action or exposure resulting from different emission sources. This was the case in the Annex XV restriction proposal on four phthalates in articles submitted by ECHA and Denmark [230] on 1 April 2016[231]. The four phthalates have the same modes of action and the overall exposure cause cumulative adverse effects.

According to the study on the EU efforts to meet the WSSD Commitment, the risk assessment under REACH considers the risks of single substances in isolation, and does not consider the effects of substances acting in combination, overlooking the normal situation whereby chemicals interact and present combined exposure to the environment and to humans. This study stresses that the combination effect undermines the traditional risk assessment approach since every similarly acting chemical in a combination contributes to the overall mixture effect, in proportion to its potency and dose. This study quotes a 2010 report[232] which states that REACH does not currently provide a mandate for considering the toxicity of so-called "coincidental" mixtures of industrial chemicals – multicomponent cocktails that are found in the environment or the human body as a result from the concurrent use of different chemicals in a given area

The Commission Communication[233] on the combination effects of chemicals provides a framework to further assess how EU legislation, including REACH, addresses the assessment of combination effects of chemicals.

The progress of this further assessment will be reported separately by the Commission. Further, combination effects are mentioned in the 7th Environment Action Programme and will feed into the Commission's future chemicals strategy for achieving the objective of a non-toxic environment.

6.4.1.3. Stakeholder views

While almost all respondents from industry associations think that REACH is the most suitable instrument with which to consider these emerging issues, among business REACH plays a secondary role.

Public authorities consider to a larger extent than other stakeholder groups that REACH is the most suitable instrument to deal with all of the emerging issues mentioned. NGOs are somewhat in between, thinking that REACH is the most suitable instrument concerning the different issues.

[230] In co-operation with Danish EPA.
[231] Available from http://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions/-/substance-rev/13107/term
[232] KEMI (2012) Improved EU rules for a non-toxic environment, KEMI Report 1/12, Gothenburg, Sweden
[233] COM (2012) 252

6.4.1.4. General Conclusions

Overall REACH appears to be able to adapt to scientific advances.

Two issues that will merit further investigation since 2013 are the review of registration requirements for low tonnage substances and the need to register polymers. Further information is necessary to assess the affordability of additional information requirements for low tonnage substances or to identify relevant polymers that could be subject to registration.

With regards to testing methods, the update mechanisms of REACH allow in principle for its adaptation to evolving scientific knowledge, for example, through updates of technical annexes and guidance. However, in practice, the adaptation of the technical annexes has been hindered by the need to address diverging scientific views (see section 6.4.1.2. Nanomaterials) and deal with administrative procedures applicable to EU legislation (time, resources, translation of technical content).

REACH is addressing emerging issues by increasing knowledge and addressing current gaps. Nonetheless, some challenges have been identified, generating relevant and specific information for nanoforms of substances, ensuring the identification of endocrine disrupting properties and addressing the combination effects of chemicals. Efforts are still needed to reflect on ways to integrate scientific developments into REACH so that it further addresses those emerging issues. With regards to the issue of nanomaterials, the ongoing revision of the REACH annexes[234] should lead to a proportionate response to clarify the registration requirements for nanomaterials.

6.4.2. IS REACH RELEVANT TO EU CITIZENS?

Assessment question: "To what extent is REACH relevant to the EU citizens?"

Europe's citizens are concerned about being exposed to hazardous chemicals in their daily life and REACH responds directly to these concerns. The perception on chemical safety has improved in the last 10 years, although the perceptions of safety vary also considerably between Member States and citizens will need further reassurance.

What is the issue?

What concerns do Europe's citizens have about chemicals and how adequately does REACH respond to this – through provision of information and management of risks.

6.4.2.1. Citizens' relevance

The EU chemicals acquis, and REACH in particular, is expected to increase confidence in chemicals of consumers, investors, workers and the general public. However, most EU citizens would not be specifically aware of REACH as the overarching chemicals legislation nor would they be able to distinguish between REACH and other chemical related legislation (e.g. CLP, biocides, pesticides, ecolabel, cosmetics, detergents or toys). Therefore, citizens' views and attitudes towards chemical safety and governance of chemicals gathered through a Eurobarometer survey in 2016[235] are most likely related to

[234] Currently under Comitology procedure , Article 133 of REACH

[235] A Eurobarometer survey was carried out at the end of 2016 to get citizens views and attitudes towards chemical safety and governance of chemicals – Link to the Eurobarometer survey on chemical safety

the overall EU chemicals acquis and not specifically to REACH. According to the Eurobarometer:

- Around two-thirds of EU citizens are concerned about being exposed to hazardous chemicals in their daily life.
- Less than half of the respondents feel well informed about the potential dangers of the chemicals contained in consumer products, with a considerable geographical variation. In northern Europe, especially in the Nordic countries, they tend to feel better informed than in southern Europe.
- Similarly to the pattern identified in 2012[236], citizens consider that product safety has improved in the last 10-15 years.
- EU citizens views are divided over the safety of products containing chemicals and perceptions of safety vary also considerably between Member States. Citizens are inclined to think that products manufactured in the EU contain safer chemicals than those imported from outside the EU, although three in ten say that none of the products are safe. This is very similar to the findings from 2012. It indicates a higher level of confidence in the EU regulatory framework for manufactured products compared to non-EU regulatory regimes.
- Half the respondents say that the current level of regulating chemicals and the current availability of standards in the EU are not high enough to protect human health and the environment and should be increased.
- Two-thirds of citizens stated that retailers are obliged to provide information, upon request, on the presence of particularly hazardous chemicals in products.

REACH can play an important role in helping EU citizens make informed decisions about their use of chemicals. In 2016, ECHA improved the presentation of its dissemination pages[237] which provide information on chemicals in three different levels of detail, tailored to the general public, workers, authorities and other stakeholders.

Table 6: illustrates how the number of visits to ECHA dissemination pages has been increasing over the last years[238].

Number of visits to ECHA dissemination pages	2012	2013	2014	2015	2016
Visitors	331 000	355 000	650 000	948 000	Over 1 million
Page views	468 000	675 000	757 000	1 816 000	10 281 286

If more and better hazard information is available on substances used in everyday products, this would encourage the use of safer alternatives available on the market. In a

[236] Eurobarometer Flash 361

[237] Information on Chemicals - ECHA

[238] In 2016 ECHA revamped their website and the current number is not comparable to the previous one

few countries, authorities and NGOs have put in place tools[239] to inform citizens about the presence of SVHCs in consumer articles. These are web-based or mobile applications to retrieve available knowledge on substances present in an article (usually by scanning the bar code) and/or to facilitate the submission of a consumer request to article suppliers. Such tools are usually accompanied by awareness raising campaigns and are facilitated by REACH's provision of information.

Taken together, this information suggests that REACH is relevant as it helps tackle real concerns amongst Europe's citizens over their exposure to chemicals. Obviously, chemical legislation has an impact on citizens' health: for example, the reduced prevalence of nickel-sensitisation in some countries since the introduction of restrictions for the use of nickel in 1994 and more recently the restriction on chromium VI in leather articles. Other measures with direct effects on citizens are the ban of carcinogenic, mutagenic and reproductive substances on their own or in mixtures, the restrictions of metals such as cadmium in jewellery or the ban of dichloromethane in paint strippers.

As REACH implementation progresses, and over time, it is expected that similar concrete effects will become more evident, as for example in relation to environmental protection.

According to the replies to the public consultation, stakeholders generally consider that REACH addresses the key issues related to chemical risks. NGOs, trade unions and public authorities are particularly positive about the relevance of REACH, whereas businesses are more critical.

Conclusions

Europe's citizens are concerned about being exposed to hazardous chemicals in their daily life and REACH responds directly to these concerns. The perception on chemical safety has improved in the last 10 years, although the perceptions of safety vary also considerably between Member States and citizens will need further reassurance.

6.4.3. ARE STAKEHOLDERS PROPERLY INVOLVED IN REACH?

Assessment question: "To what extent is REACH capable of taking into account health, consumer concerns, environmental, social and economic consequences that are relevant for citizens and stakeholders (through stakeholder information, consultation or involvement)?

Stakeholder participation has improved in the different REACH processes, in response to the large number of procedures and tools set up to inform stakeholders early on about ongoing or planned activities and to collect relevant information. Overall, this suggest that REACH is able to take into account relevant concerns, although there is room for improvement concerning the dissemination of public consultations, the transparency about the consideration of the input gathered and the better communication between stakeholders and Member States.

What is the issue?

[239] See Annex 4. Section 4.1.3

REACH involves the provision and dissemination of information and the use of this information to better manage chemicals. Stakeholders can make a valuable contribution to the effective and efficient operation of REACH through the provision of relevant information and, from the other side, providing stakeholders with relevant information allows for better and more efficient management of chemicals.

6.4.3.1. Responding to stakeholders

Consultation activities

REACH's operation includes a number of measures to allow stakeholders to be informed, including:

- REACH requires publication of intentions to initiate regulatory actions in relation to restriction of substances well before submission of the respective Annex XV dossier.
- REACH requires that ECHA conducts public consultations when (1) examining testing proposals; (2) examining proposals for the identification of substances as SVHC for the candidate list; (3) preparing recommendations for prioritisation of substances from the candidate list to be included in Annex XIV and (4) assessing applications for authorisation of SVHCs or proposals for restriction.
- ECHA publishes annual draft updates of the Community Rolling Action Plan of substances to become subject to evaluation (covering a three-year period from year N to N+2).
- the Commission launched in 2014, 2015 and 2017 calls for information on socio-economic aspects of the possible inclusion of substances into Annex XIV in parallel with ECHA's calls for information on draft recommendations for prioritisation of substances.

Stakeholders' participation[240] in the public consultations depends largely on the topic sub and the ability to consolidate comments efficiently; for example, public consultations related to testing proposals received over 800 comments[241], mainly from NGOs (over 90% of comments in some cases), public consultations related to SVHC identification received over 500 comments[242] from a wider range of stakeholders (44% industry, 29% Member States, 24% NGOs). The Commission received 490 replies to the first two calls for information on socio-economic aspects of inclusion of substances in Annex XIV from industry stakeholders (associations and particular companies).

This shows that public consultations provide a channel for all stakeholders' concerns to be fed into REACH decision-making. However, several categories of stakeholders want to improve the dissemination, timing and duration[243] of the consultations to allow for effective input from stakeholders. ECHA and the Commission publish on their websites, responses-to-comments reflecting how the comments received have been addressed.

In the case of the restriction process, the duration of the public consultation is 8 months, a long time compared to other Union legislation, although ECHA continues to receive

[240] The number of comments received is presented for illustrative purposes. In recent years, industry has begun to consolidate their comments, e.g. by sending one submission covering all points from e.g. the relevant trade association. This has brought many efficiencies in handling these cases.

[241] Public consultations carried out in relation to testing proposals since 2009

[242] Public consultations carried out in relation to proposals for SVHC identification between 2014 and 2016

[243] For example public consultations on testing proposals

comments close and after the deadline. Questions have also been asked during the public consultation in order to attract the attention of stakeholders on the need to receive specific input during the restriction procedure.

Representatives from SME organisations have pointed to difficulties due to the high number of public consultations and the absence of translations into all EU languages of the consultation documents. Some industry stakeholders have also expressed dissatisfaction with the way ECHA and the Commission integrate input from public consultation in their decisions as well as their concern about the possible misuse of public consultations as marketing tools by certain suppliers of alternatives to substances under consideration for authorisation.

Some NGOs have also expressed dissatisfaction on the type of comments submitted by industry during the public consultation and how the ECHA Committees evaluate this information. As regards the authorisation procedure, NGOs consider that the analysis of alternatives should be better assessed by the ECHA Committees and by the Commission.

Public Activities Coordination Tool

Besides the mechanisms envisaged in REACH as legal requirements (registry of intention and public consultations), an important measure to inform and involve stakeholders in planned actions under REACH, is the establishment by ECHA of the Public Activities Coordination Tool (PACT)[244] as part of the implementation of the SVHC Roadmap 2020.

The PACT gives early signals to all stakeholders, and in particular also to industry, by listing substances for which a regulatory management option analysis (RMOA) or an informal hazard assessment for substances with persistent, bioaccumulative and toxic and very persistent and very Bioccumulative (PBT/vPvB) properties or endocrine disruptor properties is either under development or has been completed. Industry uses this warning to ensure that registration dossiers are up-to-date and to be aware of possible actions under the Roadmap.

PACT is an important communication tool in the context of the implementation of SVHC Roadmap to improve transparency and predictability for stakeholders**.** The study *Monitoring the impacts of REACH on innovation, competitiveness and SMEs* states that during the interviews all stakeholders welcomed PACT**.**

The impact of the publication of the PACT and how stakeholders work together with Member States in further regulatory actions under REACH needs to be further explored. In addition, ECHA launches a call for evidence allows interested parties to provide input very early on in the restriction process.

Further stakeholder involvement

Stakeholders are also involved in the practical implementation of REACH by participation in the development and amendment of Guidance documents (through the partner expert groups organised by ECHA) and through the meetings of Member State competent authorities for REACH and CLP ("CARACAL"), which advises the European Commission and ECHA on important REACH and CLP interpretation and implementation issues, and include as observers a limited number of key stakeholders including from industry, trade unions, NGO's and trading partners.

[244] The PACT went online in September 2014

In addition, REACH requires ECHA to develop appropriate contacts with stakeholders. ECHA has implemented its stakeholder management activities[245] along three main lines: broad communication and events aimed at all stakeholders (such as stakeholders days, website, newsletters and helpdesk), events and communication targeted at specific stakeholder groups (e.g. workshops for industry and Competent Authorities) and specific roles and privileges for its accredited stakeholders (such as the right to attend ECHA Committee meetings). 100 organisations are listed as Accredited Stakeholder Organisations on ECHA's website[246]. Stakeholders (industry, trade unions and NGOs) also have a seat each as observers in ECHA's Management Board.

Regarding the stakeholder involvement at national level, the Analysis of Member States' reporting questionnaire states that involvement of companies during the preparation of Annex XV SVHC identification and restriction dossiers by Member States and ECHA has been limited**.** However, several Member States are actively engaging with stakeholders when conducting RMOAs and others have found difficulties to have industry stakeholders engaged in the discussion in particular during the preparation of the Annex XV dossier for restriction.

Overall the Stakeholders participation has been constructive during the preparation of guidance as well as during the policy discussion in CARACAL.

6.4.3.2. Conclusion

The REACH Regulation includes a number of mechanisms enabling stakeholders to participate in the decision-making processes. Stakeholder participation has improved in the different REACH processes, in response to the large number of procedures and tools – both with and without legal requirements in REACH – that have been set up to inform stakeholders early on about ongoing or planned activities and to collect relevant information early during the implementation of the different REACH processes or to trigger updates of registration dossiers.

It can be concluded that the REACH procedures allow citizens and stakeholders to present their views and relevant information, although there is room for improvement concerning the dissemination of public consultations, the transparency about the consideration of the input gathered and the better communication between stakeholders and Member States.

6.5. EU added value

6.5.1. WHAT IS THE EU ADDED VALUE OF REACH?

Question VA1: What is the additional value of regulating the risk management of chemicals at EU rather than at Member State level?

There is clear EU added value to having REACH and regulating the risk management of chemicals at the EU rather than at the Member State level. The EU approach offers advantages in terms of effectiveness and avoiding a fragmented approach in a market where firms are increasingly cross border in their outlook. There are also synergies

[245] Link to Stakeholders website - ECHA

[246] December 2016

reflected in better value for money from cross border legislation of chemicals.

6.5.1.1. Analysis of EU value added

The effectiveness and efficiency sections provide relevant analysis on how REACH contributes to the risk management of chemicals at EU level, cooperation and coordination between Member States as well as international cooperation. The conclusion that REACH is proving to be effective and that it is efficient, in the sense that the costs seem to be justified by the benefits, already suggests that it has EU value added.

Moreover, REACH is the only European legislation which provides a comprehensive risk assessment of chemicals from all the different sources and routes of exposure and can also cover not only individual chemicals but also group of substances. REACH may also complement other legislation where the risk of chemicals is not adequately controlled. For example, a restriction for industrial use can be initiated also for those chemicals which have an occupational exposure limit value set up at Union level if it is demonstrated that the risk is not adequately controlled. The situation has clearly changed since the adoption of REACH. REACH transferred the burden of proof to the industry as regards the safety of chemicals placed on the EU market, with uniform rules that apply across Member States. This has increased the knowledge on properties, uses, emission/exposure and risks of chemicals manufactured and imported in Europe. The increased knowledge about chemicals and enhanced communication in the cross-border supply chain enables all actors (manufacturers, importers and downstream users) to take the necessary measures to ensure safe use and consumers to gather a better knowledge on chemicals used during their daily life.

REACH has helped to avoided fragmentation in the European market. EU level intervention brings consistent rules to create a level-playing field for the economic operators in the EU market, avoiding differences that would clearly have occurred if REACH objectives were pursued by individual Member State actions. Since REACH's adoption, cross-border flows have increased although whether this is because of REACH or simply a reason for REACH is unclear.

The implementation of the REACH Regulation at the EU level also offers better value for money by allowing for resources, expertise and information to be better shared and co-ordinated, in a way that delivers efficiency. For example, REACH requires sharing of the workload (e.g. SVHC identification, restriction proposals) and exchanging knowledge between the public authorities as well as enhancing the coordination of their approaches between the different departments. Different bodies and activities organised to exchange expert opinions and coordinate the views of different national authorities such as the European networks created (e.g. CARACAL, HelpNet, Forum) facilitate the coordination of Member State activities, ensuring coherence between risk assessment practices at national level and avoiding duplication of work. Member States are therefore more efficient than if they were working in isolation. Moreover, having an EU central body like ECHA produces cost-savings in terms of the time and resources needed by Member States e.g. as registration is done centrally and not at national level and provides increased visibility of EU activities in international fora (e.g OECD and UN).

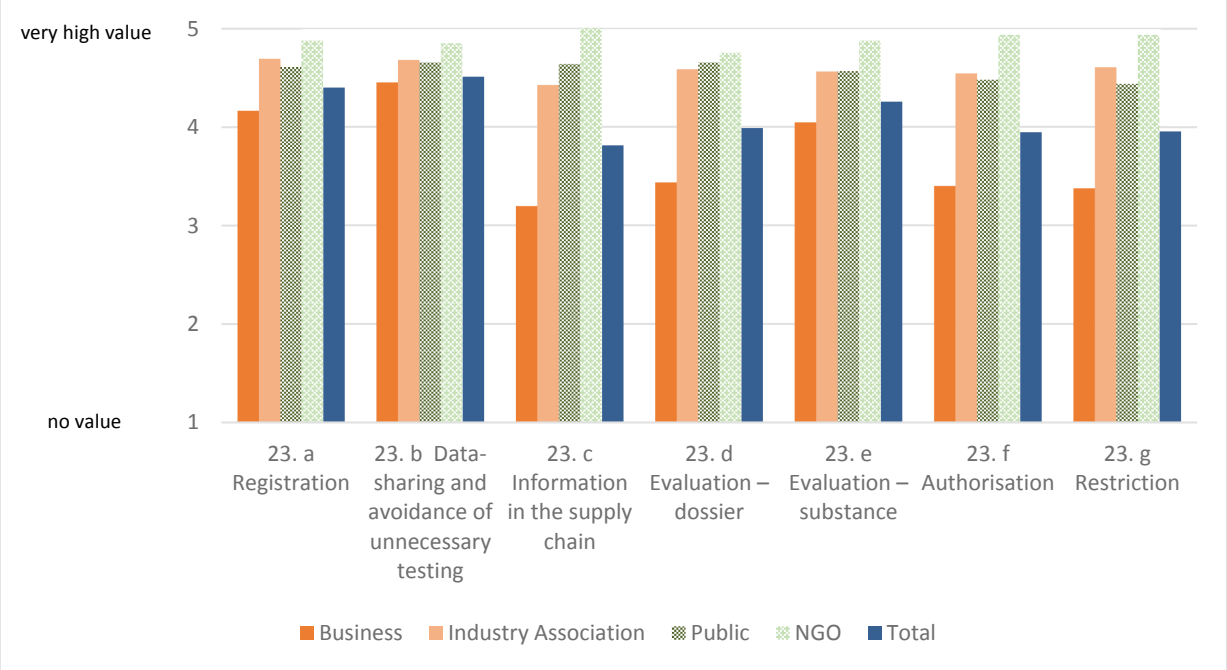
Moreover, the objectives of REACH – high level of protection of human health and the environment, the internal market for chemicals and the competitiveness and innovation of industry - remain relevant for the EU and its citizens. This can be shown by the harmonisation effects of the restrictions proposal where Member States consider the protection of human health and the environment a goal for all European citizens and therefore prefer to act under REACH rather than at national level. Impacts both on

human health and the environment are often cross border. Similarly, the Commission considers that the risk of chemicals is better addressed if the measures to limit their risks are implemented at EU level as this provides the same level of protection of human health and the environment and allows for consistent control of imports at the EU border.

Some stakeholders have flagged the need for further efforts to make market surveillance and enforcement practices more aligned across the Member States as they perceive differences in the frequency of inspections and resources allocated by different Member States to ensure compliance with REACH. Nonetheless, the Forum is an effective instrument to coordinate and harmonise the national enforcement of REACH across the EU and can further improve the synergies between Enforcement Authorities and REACH Competent Authorities.

Overall, stakeholders from all groups consider that having a harmonised Union-wide approach is appropriate to manage the risks of chemicals in the EU. Respondents to the online public consultation expressed a very high appreciation of the EU added value achieved by the different chapters of REACH, compared to what could have been achieved through action by Member States alone at national level. Registration and data sharing and avoidance of unnecessary testing are considered of highest added value. The biggest difference between stakeholders is that respondents from individual businesses, academic institutions and individual citizens hold less favourable views, while consumer associations, NGOs and industry associations have a particularly positive view concerning the EU added value.

Figure 7: Answers to question on EU added value through the open public consultation: To what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (average values by stakeholder group on a scale from 1=no value to 5=very high value)



Conclusion

There is clear EU added value to having REACH and regulating the risk management of

chemicals at the EU rather than at the member State level. The EU approach offers advantages in terms of effectiveness and avoiding a fragmented approach in a market where firms are increasingly cross border in their outlook. There are also synergies reflected in better value for money from cross border legislation of chemicals.

7. CONCLUSIONS

This Staff Working Document presents the findings of the evaluation of the REACH Regulation. It has been carried out on the basis of Member States reports and on the inputs from those involved in implementing the Regulation, including through detailed feedback received as part of the stakeholder consultation process, as well as a result of the continuous dialogue that the Commission maintains with Member States and stakeholders.

REACH is being fully implemented, and all its processes are operational. Key milestones have been met thanks to the effective cooperation between the Commission, ECHA, Member States, duty holders and other stakeholders.

The follow-up to the 2013 REACH review by the Commission, Member States and ECHA led to important improvements; however, there is still a need to improve certain specific REACH processes in order to make the system more workable and efficient, in particular, authorisation evaluation and restriction.

Ten years after entry into force, this REACH evaluation confirms the relevance and achievability of the objectives of REACH: to have a European chemical legislation which protects human health and the environment, promotes alternative methods for the assessment of substances' hazards and strengthens the internal market while promoting competitiveness and innovation.

Effectiveness of REACH

Progress has been made towards achieving the REACH objectives, as evidenced by the outcomes delivered so far. Although this progress is lagging behind the initial expectations of 2006, the progress has steadily improved and expectations recalibrated. The different building processes and actions envisaged in the intervention logic of REACH are being largely implemented, which suggests that REACH is protecting human health and the environment. REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort has been implemented at the expense of hazard information relevant for the protection of human health and the environment. REACH has strengthened the internal market thanks to further harmonisation of its governing rules. The result of several stakeholder surveys did not provide a clear picture if REACH generated an increase of intra-EU trade.

More information on the properties and uses of chemicals is available and being used for the assessment and management of risks, indicating that REACH has improved the protection of human health and the environment. Some specific evidence confirms the progress towards the expected results at this stage (such as in more information provided in the registration dossier, in the improved communication through the supply chain, in the reduction of chemical risk). Evidence also confirms that the benefits are starting to materialise, even if most of them will first occur in the coming years. However, the shortcomings in relation to the high level of non-compliance of the registration dossiers, the insufficient flow of information along the supply chain and the challenges associated

with the evaluation, authorisation and the restriction processes are slowing down the delivery of those benefits. As stated in the legal text, REACH's provisions are underpinned by the precautionary principle, however, since the entry into force of the legislation, the risk management actions proposed by the Commission have been limited. The development and consideration of alternative methods have greatly improved during the last ten years, although at the expense of the hazard information being delivered to Member States and hence at the expense of the protection of human health and the environment.

Regarding the free circulation of substances on the internal market, REACH is delivering further harmonisation of its governing rules and thus seems to be supporting the intra-EU trade. However, whilst the enforcement seems to have improved, further efforts to ensure compliance with REACH are needed at Member State level to better achieve a level-playing field across the EU.

The effects of REACH on competitiveness and innovation are difficult to quantify. There is some limited evidence of increasing innovation, but it is difficult to say whether this is due to REACH or not. It is also hard to clearly distinguish the impact of REACH on competitiveness as, again, competitiveness depends on many other important factors, such as the increasingly global market and the global economic developments.

REACH is leading to some other effects, either expected or unplanned. For example, REACH is increasing the expertise of public authorities and industry on chemicals and it has become a benchmark for third countries in terms of chemical regulation, thus contributing to international harmonisation in the implementation of chemicals policy. REACH provides a comprehensive data generation and assessment of most chemicals, compared to non-EU regimes that focus only on new and/or prioritised chemicals. Hence, REACH has also led to a vast publicly available database on chemicals, unique in the world. Other effects have been reported by industry stakeholders although limited evidence has been produced in this respect: market concentration, withdrawals of substances from the market, competitive advantage for non-EU producers of articles and possible business relocation.

The effective collaboration between the Commission, ECHA and Member States Competent Authorities has been a key factor to enhance the effectiveness of all the REACH processes. This coordination helped improvements in the implementation of the evaluation, authorisation and restriction processes as well as in identifying substances of very high concern by the SVHC Roadmap.

All the above has resulted in considerable progress towards meeting the World Summit Sustainability Development 2020 goal, positioning the EU as the strongest promoter.

Efficiency of REACH

In general, the costs of REACH seem to be justified by the expected benefits that are starting to materialise. The cost for businesses to meet the obligations of the first two registration deadlines (these being the costliest of the processes in REACH so far), was around EUR 2.3 billion, which although higher than expected (EUR 1.7 billion), is in the same order of magnitude expected. On the other hand, even though it is still too early to conclude, the benefits are progressively materialising. For the

time being, whilst the total costs seem justified and the efficiency has improved over time, there is still further scope for improvement, by simplifying and reducing the regulatory burden, whilst enhancing the delivery of benefits.

Benefits have started to materialise, but most of the benefits will first occur in the coming years. The first signal of benefits observed are the effects of the adopted restrictions on chemicals for human health and the environment, the improvement of risk management in the workplace, the better knowledge of chemicals, the substitution of substances of very high concern and the improvement of the communication through the supply chain.

The implementation of REACH brings costs for duty holders and public authorities. The main source of costs for duty holders is the registration process, which resulted in costs higher than originally predicted in the extended Impact Assessment, but in the same order of magnitude. Compulsory data sharing was the main factor increasing the costs compared to the original expectations. The cost of the first two registration deadlines was around EUR 2.3 billion spread over seven years (in the context of a chemicals sector which had sales of more than EUR 3500 billion over seven years). Included in the registration costs for businesses are the fees paid to ECHA, which between 2008 and 2016 were EUR 581 million – of this at least EUR 136 million were paid by representatives of non-EU producers. These costs are higher than the Commission estimates, which can, at least partly, be due to the additional costs of the "one substance, one registration" requirement introduced in REACH by the co-legislator and the lower use of QSARs compared to what was anticipated.

As regards public authorities, the costs at EU level have been slightly below the expectations as a result of the – 14% higher than foreseen – fees and charges revenues collected by ECHA by 2016. However, there has still been an EU balancing subsidy to ECHA totalling EUR 247 million, and EU funding of research on alternative methods of around EUR 40 million per annum. The resources available for Member States' activities vary widely and some REACH processes, namely the evaluation of substances or the restriction proposals, are driven by a relatively small group of Member States.

The registration costs are the largest cost factor for businesses, but there are also costs linked to the communication in the supply chain, evaluation, authorisation process or restrictions put in place: the costs quantified for these processes so far are justified by the positive results observed. The costs of applying for individual authorisations, for example, have halved since 2013 but the overall cost and benefits for implementing the authorisation process remain unknown.

The concerns described in the 2013 REACH review about the impact on SMEs remain, especially in view of the forthcoming registration deadline (2018), where many more SMEs are expected to be involved. On the other hand, the support measures put in place including the further reduction of fees are perceived as useful to assist them in complying with the REACH provisions.

The need to improve the efficiency of the REACH processes had been underlined in the 2013 REACH review and, since then, a number of improvements have been implemented or are being developed to improve the efficiency (e.g. registration) or to simplify the processes (e.g. authorisation and restriction). Further opportunities for improvement and simplification have been identified, namely in relation to the extended Safety Data

Sheets, the process of applying for authorisation, the preparation of restriction dossiers, the evaluation process and the requirements for substances in articles.

Coherence of REACH

The different actions under REACH link well together and largely deliver internal coherence, although the weaknesses identified in registration dossiers and the insufficient flow of information in the supply chain hinder the functioning of the subsequent REACH processes. REACH also seems to be largely consistent with other EU legislation, but some incoherencies affecting recycled materials and occupational safety and health legislation have been observed and need to be addressed.

Whilst the different REACH processes link well together there are weaknesses in registration dossiers and in the subsequent flow of information along the supply chain. This hinders subsequent REACH processes and, for example, the identification of appropriate regulatory measures (authorisation or restriction). However, the flow of information has improved since the REACH Review 2013, and efforts are ongoing to improve it, especially in light of the increasing operational experience. For example, the integrated regulatory strategy and associated common screening developed by ECHA in recent years is a significant contribution to improving the way the REACH processes work together.

When analysing the coherence between REACH and other EU legislation, some critical elements have been identified and addressed in the interface with RoHS and POPs. Further efforts are needed to assess other pieces of EU legislation and analyse their coherence with REACH and their added value. Currently the following actions are being undertaken:

- The interface of REACH and occupational safety and health legislation (OSH), where the overlaps have started to be tackled, such as the different limit values of exposures and the different methodologies for the same chemical substance.
- The interface of REACH with the Waste framework legislation affecting recycled materials, where a roadmap has been published and issues will be tackled in the context of the Circular Economy by the end of 2017.

The general coherence between the different EU agencies and the Scientific Committees needs to be improved to allow for better regulation, including more harmonisation between the different methodologies applied by these bodies.

REACH is coherent with the chemicals policy in third countries, and there are some signs of harmonisation (in terms of objectives or tools). The current international activities with the active contribution of the Commission and Member States ensure a more consistent approach to chemicals management in the world.

Relevance

REACH appears to be generally able to adapt to continuous scientific advances. REACH also responds to citizens' concerns, and is improving public perceptions of

chemicals, with stakeholders involved in the decision-making process.

REACH operates in a context of continuous scientific and technical progress, with new products and testing methods constantly being developed. Generally, the mechanisms of REACH to adapt to this constant change via updates are generally working, although in some specific areas such as the obligation to update registration dossiers, it has been found that they are not delivering.

It can be concluded that REACH responds directly to the concerns of citizens about being exposed to chemicals in their daily life and is contributing to an improved public perception of chemical safety. Stakeholder participation in the REACH processes has improved and their concerns are taken into account by the Commission and ECHA in the decision-making processes, although there is room for increased transparency.

The relevance of the registration requirements for substance in low tonnages (1-10t) and for polymers to ensure environmental safety and human health have been examined in this evaluation. For substances in low tonnages, options improving health and environmental benefits have been identified and will be further examined, considering also the experience gained with the last registration deadline of 2018 and their likely impact on SMEs. The Commission will also further investigate how to identify and group polymers of concern for human health and the environment with a view to establish the need, if any, of a legislative proposal.

EU added value

There is clear EU added value to having REACH and regulating chemicals at the EU level rather than at the Member State level. This is both more effective and efficient.

There is clear EU added value resulting from the implementation of REACH. Addressing chemical risks at EU level rather than at Member State level clearly offers advantages. In terms of effectiveness, it avoids a fragmented approach in a market where activities of firms are increasingly cross border. It also allows public authorities to pool their resources together and share the workload. Thus, there are synergies reflected in better value for money from cross border legislation for chemicals.

REACH provides a comprehensive assessment approach covering all the different sources and routes of exposure. The wider range of risk management measures available (in addition to the restrictions, in particular the authorisation process) are progressively leading to the identification and effective control of more hazardous substances by public authorities, as well as substitution of substances of particular concern for human health and the environment. Moreover, the increased knowledge about chemicals and the extension of responsibility along the supply chain are also leading to improved risk management procedures and responsibility in companies. ECHA has demonstrated the EU added value in the implementation of REACH and CLP.

Overall conclusion and need for improvement

Ten years after the entry into force, the objectives of REACH – high level of protection of human health and the environment, the internal market for chemicals and the

competitiveness and innovation of industry, remain relevant for the EU and its citizens. Moreover, the EU-level intervention is providing a more effective and efficient means to achieve such objectives than action by individual Member States.

The functioning of REACH has improved in response to the conclusions of the REACH Review 2013, with a number of changes being put in practice in response to the experience gathered and the feedback of stakeholders. Further room for simplification, reduction of the regulatory burden by clarifying the incoherencies between REACH and other Union legislations and improvement of the effectiveness have been identified.

The issues requiring most urgent action are:

- Non-compliance of registration dossiers: work is still needed to rectify the important data gaps or the inappropriate adaptations in the registration dossiers. Greater incentives may be needed for companies to update their registration dossiers as required by REACH, especially on the use, exposure and tonnage information.
- Simplification of the authorisation process: ongoing efforts to streamline and simplify the authorisation process should continue with a view to clarifying the requirements and make the process more predictable. The SVHC roadmap provides an effective and efficient system to identify relevant SVHCs and possible regulatory measures. In parallel, efforts must be stepped up to promote substitution of very high concern chemicals, in particular among SMEs.
- Level playing field with non-EU companies: in order to ensure the same level playing field between economic operators in and outside the EU, it is important that ECHA takes all possible preparatory steps in the lead up to the sunset date in order to expedite the assessment of the need for a restriction on imported articles containing substances listed in Annex XIV. Moreover, enforcement activities by Member States, in particular for imported goods, needs to be reinforced.
- Coherence: further activities are needed to clarify the coherence between REACH and other pieces of EU legislation. Work should continue on the coherence between REACH and OSH and waste legislation.

Further issues to be addressed are:

- The review of registration requirements for low tonnage substances and the need to register some polymers merit further investigation.
- The tools put in place to support the downstream users in meeting their obligations as regards the communication in the supply chain and the development of extended Safety Data Sheets should be further disseminated and their use improved.
- There is a need to consider how dossier and substance evaluation can move towards further addressing dossier deficiencies and concerns of high volume substances, but also towards the assessment and improvement of lower tonnage registrations, and eventually to monitoring the continuous compliance of all the dossiers in light of the technological and scientific development and the registration of new substances.
- The number of restrictions has so far not met the original expectations, but the process

has been improved on the basis of the recommendations resulting from of the Task Force (Commission services, ECHA and Member States as well as members of RAC and SEAC) e.g. through common screening and regulatory management option analysis..

- There is room for further improvement in the restriction process, on the basis of the recommendations of the Task Force, which are being implemented but are considered "work in progress". The activities should continue on the basis of the experience gained in the preparation of Annex XV dossiers. ECHA should review the requirements for the conformity check and continue its efforts to obtain a maximum of information through the public consultation. RAC and SEAC should diligently scrutinise the information submitted in the dossier and via the public consultation, including in particular requests for exemptions. Efforts to ensure compliance with the REACH provisions across the EU and achieve an effective level-playing field should be stepped up.
- The further development of enforcement indicators must be pursued to ensure monitoring.

ANNEXES

Annex 1 – Procedural information concerning the process to prepare the evaluation

Annex 2 – Stakeholder consultation

Annex 3 – Methods and analytical models used in preparing the evaluation

Annex 4 – Implementation state of play

Annex 5 – Horizontal issues

Annex 6 – Review of ECHA